



STATE OF TENNESSEE
DEPARTMENT OF HEALTH

JOHN J. DREYZEHNER, MD, MPH
COMMISSIONER

BILL HASLAM
GOVERNOR

March 17, 2015

Ms. Melanie Hill, Executive Director
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

HAND-DELIVERED

RE Certificate of Need Applications: No. CN1407-027 filed by Implanted Pump Management LLC; No. CN1411-046 filed by Pentec Health Inc.

Dear Director Hill:

The Tennessee Department of Health (TDH) has completed its review of the above-referenced Certificate of Need (CON) applications that are set to be heard on March 25, 2015. TDH would like to ensure that the Health Services and Development Agency (HSDA) is aware of our concerns regarding the following matters:

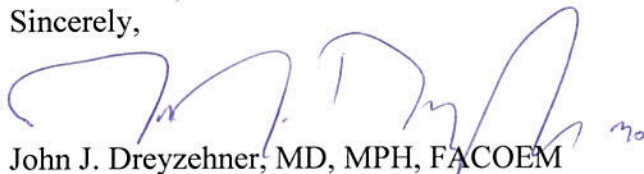
1. The applicants' plans may or may not be consistent with the federal and state requirements related to delivery of controlled substances. Federal law assumes a "dispenser" delivers a controlled substance to an "ultimate user," and the rules of the Tennessee Board of Pharmacy require face-to-face patient or caregiver counseling when dispensing drugs. TDH believes that clarification is needed regarding the applicants' plans for transport of these controlled substances.
2. Also regarding controlled substances, the applicant must have written policies addressing personnel training and oversight related to drug diversion and drug screening.
3. TDH notes that the applicants propose to contract with out-of-state compounding pharmacies, despite the fact that the state Board of Pharmacy protects the health and safety of patients in Tennessee by regulating approximately 240 compounding pharmacies in the state. TDH has greater assurance of protecting the health of people in Tennessee when the compounding pharmacies are located in Tennessee and therefore inspected for quality.
4. TDH expresses concern that one applicant (CN1407-027, Implanted Pump Management LLC) and its compounding pharmacies have been the subject of disciplinary actions.

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5. In order for a home health agency to receive federal reimbursement, a patient must be “homebound.” However, this requirement is for federal reimbursement not state licensing; therefore, it is not an issue for TDH licensure.
6. The applicants’ office/staffing plan, nurse contract, and all policies and procedures will be reviewed and used during surveys by the Division of Health Licensure and Regulation.
7. TDH is not confident that the physicians to whom the nurses report have a sufficient level of intrathecal pump expertise, and therefore requests information regarding this expertise.
8. TDH would like to make the HSDA aware of practice guidelines published in December 2014 by the American College of Occupational and Environmental Medicine regarding opioids for treatment of acute, subacute, chronic, and postoperative pain¹. The guidelines directly address intrathecal opioid treatment, saying: “No quality studies document efficacy of intrathecal opioid delivery systems for treatment of chronic nonmalignant pain. Intrathecal opioid delivery systems are invasive and costly, with possible significant adverse effects, including potential long-term sequelae from both implantation/retention of the devices, including granuloma formation, and those associated with the concurrent use of intrathecal opioids. Thus, with a lack of documented efficacy, invasiveness, serious adverse effects, and marked costs, these devices are not recommended.”

TDH appreciates the opportunity to provide comments regarding these CON applications, and we hope that this information is helpful to the HSDA. On balance, we have concerns regarding the unintended consequences that may result from these services and the overall impact they may have on population health in Tennessee.

Sincerely,

A handwritten signature in blue ink, appearing to read 'J. Dreyzehner', with a small 'no' written to the right.

John J. Dreyzehner, MD, MPH, FACOEM
Commissioner

¹ Hegmann, K.T., et al. (2014, December). ACOEM Practice Guidelines: Opioids for Treatment of Acute, Subacute, Chronic, and Postoperative Pain. *Journal of Occupational and Environmental Medicine*, 56 (12), e143-e159.

**HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING
MARCH 25, 2015
APPLICATION SUMMARY**

NAME OF PROJECT: Pentec Health, Inc.

PROJECT NUMBER: CN1411-046

ADDRESS: 424 Church Street, Suite 2000
Nashville, (Davidson County), Tennessee 37219

LEGAL OWNER: Pentec Holdings, Inc.
4 Creek Parkway
Boothwyn, Pennsylvania 19061

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Doug Wynd
Pentec Health, Inc.
4 Creek Parkway
Boothwyn, Pennsylvania 19061
(800) 223-4376

DATE FILED: November 14, 2014

PROJECT COST: \$142,028

FINANCING: Cash Reserves

PURPOSE FOR FILING: Establishment of a home care organization and the initiation of specialized home health services related to home infusion for patients with implanted intrathecal infusion pumps and patients receiving immunoglobulin-G replacement therapy in all counties of Tennessee except Hancock, Perry and VanBuren Counties.

DESCRIPTION:

Pentec Health, Inc. is requesting approval to establish a home care organization and provide specialized skilled nursing services for patients with surgically implanted intrathecal pumps under physician's orders. The applicant also

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proposes providing skilled nursing for patients receiving immunoglobulin (Ig-G) replacement therapy through intravenous or subcutaneous infusion (as an ancillary service). The applicant's proposed specialized home health service will receive pharmacy support for the preparation, packaging and distribution of intrathecal medications from Pentec's pharmacy in Boothwyn, Pennsylvania, a specialty closed door compounding pharmacy that is licensed in Tennessee and other states. An overview of the nature and scope of Pentec nursing and pharmacy responsibilities for the proposed service is summarized on pages 6 and 7 of the 11/25/14 supplemental response.

The applicant initially proposed serving all 95 Tennessee Counties. However, due to HSDA requirements pertaining to publication of the Letter of Intent in a newspaper of general distribution, the service area was changed to a statewide service area that contains 92 Tennessee counties and excludes Hancock, Perry and VanBuren Counties. The applicant's proposed home health organization will operate from a main office located at 424 Church Street, Suite 2000 in Nashville (Davidson County), Tennessee.

SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.
2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.
The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.
3. Using recognized population sources, projections for four years into the future will be used.
4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

The applicant states that the specialized nature of the proposed skilled nursing

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service and the lack of comparable utilization data from existing agencies impacts the ability to provide an estimate of need for specialty infusion therapy services. Following Steps 1-4 above, the Department of Health report that is based on 2013 data indicates that residents of the applicant's proposed 92 county service area will need home health care in 2018; however approximately 182,973 patients are projected to be served in 2018 by existing home health organizations resulting in a net excess or surplus of (80,773).

It appears that this application does not meet the criterion.

5. Documentation from referral sources:

- a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

During initial staff review, the applicant states that it had been in contact with a number of practitioners in Tennessee. Their names are noted on page 58 of the application. At HSDA request, the applicant provided a December 1, 2014 letter from a physician of Comprehensive Pain Specialists located in Hendersonville (Sumner County) as an attachment to Question 5, Supplemental 2. The physician states that the medical practice is one of few providers in Tennessee that treats patients with intrathecal pumps. Although the physician mentions that his practice treats patients from all over the state, no indication is given regarding the potential number of referrals.

Since the applicant is requesting a 92 county service area, it appears that this criterion has not been met.

- b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

According to the applicant's research, there were approximately 1,976 intrathecal pump patients and 1,020 Ig-G patients in Tennessee in calendar year 2014. The applicant notes that patients requiring skilled nursing services for assistance with infusion pump medication refills, titrations, and changes in medical condition would be candidates for referrals by physicians, primarily those practicing in the areas of pain management and spasticity. Approximately 100% of the total projected utilization in Year One amounts to approximately 121 total visits consisting solely of visits Pentec will provide to implanted pump infusion

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therapy patients. However, as previously noted, the 1 physician referral letter did not specify the number of potential referrals.

It appears this criterion has been met.

- c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided no letters from potential patients during review of the application. However, there was a 12/1/14 letter from a physician of Comprehensive Pain Specialists in Hendersonville (Sumner County) that described the nature of the drug administration service requiring highly specialized nursing and pharmaceutical services.

Since the applicant is requesting a 92-county service area, it appears that this criterion has not been met.

- d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

The applicant states that the proposed services are substantially different from those provided by a traditional home health agency that may offer a variety of skilled nursing, home health aide or other clinical services such as physical therapy. By contrast, the applicant proposes limiting its services to home infusion related services for intrathecal pump infusion pump therapy and Ig-G replacement therapy patients. In response to supplemental staff questions, the applicant remarked that it was unable to confirm the extent, if any, to which other existing agencies treated intrathecal pump patients (please see page 11 of Supplemental 1 and page 11 of Supplemental 2 for further detail). Pentec's proposed specialty infusion services would be provided by trained nursing staff that are required to complete a corporate nurse training program that is approved by the American Nurses Credentialing Center. As such, the applicant maintains that these services and credentials are unique and are not typical of the average Medicare certified home health agency (a comparison of key differences is shown in the table on page 5 of Supplemental 2).

It appears this criterion has been met.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
- a. The average cost per visit by service category shall be listed.

An average gross charge of \$2,517 per skilled nursing visit and an average cost of \$2,343 per visit is projected in Year One as reflected in the Projected Data Chart of the application and clarified in the table on page 24 of Supplemental 2. Although there are no known agencies with similar services for comparison, the applicant notes that typical reimbursement by commercial plans is approximately \$92 per visit for nursing and \$50 - \$70 for per diem charges (page 41, Supplemental 1). A Table in the attachment on page 156 of the revised application provides a summary of the applicant's fee schedule for the proposed service.

It appears this criterion has been met.

- b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant projects an average daily census of approximately 20 patients per day in Year One. Based on 6 visits per intrathecal pump patient per year, the applicant's projected average charge and cost for these types of patients will be approximately \$14,826.00/patient and \$13,500.00/patient, respectively, in the first year of the project.

It appears this criterion has been met.

Staff Summary

Note to Agency members: This staff summary is a synopsis of the original application and supplemental responses submitted by the applicant. Any HSDA Staff comments will be presented as a "Note to Agency members" in bold italics.

Summary

Pentec Health Inc., an existing, unique provider of specialty infusion therapy services in 30 states accredited by the Joint Commission in both home care and pharmacy, is seeking approval to establish a home health organization and provide skilled nursing services limited to patients with surgically implanted intrathecal infusion therapy pumps or patients receiving immunoglobulin-G (Ig-G) replacement therapy through intravenous or subcutaneous infusion. All nursing services will be provided to patients in their residence statewide (excluding Hancock, Perry and VanBuren Counties), under physician ordered

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plans of care. The proposed home health agency will be located in approximately 87 square feet of leased office space at 424 Church Street, Suite 2000 in Nashville, Tennessee.

The applicant's nursing team will be on call to serve patients in the 92 county service area on a 24/7 basis. Patients will have direct contact with his/her assigned nurse through a toll free number or after office hours through a Pentec Health, Inc. central call center that will contact the appropriate nursing team member. Initial staff will consist of current licensed registered nurse employees, including individuals appointed as the proposed agency's administrator and alternate administrator. Additional licensed nursing staff will be assigned in accordance with Pentec Health Inc.'s staffing ratio of one nurse to 40 patients.

Pentec's non-resident licensed Tennessee pharmacy (#4108) will support the applicant's proposed home health operations in Tennessee. The pharmacy is licensed by the State of Tennessee (license # 4108) and is Joint Commission Accredited. The pharmacy is one of two pharmacies owned by Pentec Health, Inc. It is a specialty closed door compounding pharmacy located at Pentec's corporate headquarters in Boothwyn, Pennsylvania (the other Pentec pharmacy is located in Mansfield, Massachusetts). The pharmacy is licensed in all 50 states and the District of Columbia (*note: please see additional clarifying information on page 5 of Supplemental 1 and page 4 of Supplemental 2*). Pentec's Tennessee licensed pharmacy is actively certified for participation in Medicare and TennCare.

The payor types of home health patients to be served by the applicant will be privately insured, self-pay, or medically indigent patients. The applicant does not intend to certify its limited service home health agency for Medicare and Medicaid. The applicant will on occasion provide skilled nursing in-home services to Medicare and TennCare infusion patients on a limited basis under its Compassionate Care, No Insurance or Financial Assistance policies, as appropriate. Some financial assistance for these patients will be available on the basis of Pentec's pharmacy certification in both Medicare and TennCare.

The infusion-related in-home skilled nursing service activities required in connection with the target implanted pump infusion therapy or Ig-G replacement therapy patients are listed in detail on page 9 of Supplemental 1. Key activities include medication administration for pump refills in accordance with physician orders; assessment for side effects, adverse reactions, patient and caregiver education, assessment of pump equipment function in accordance with pump manufacturer requirements, assessing intrathecal and IV access sites and surrounding areas for possible complications, recording vital signs and collecting blood specimens when ordered by a physician. These services will be provided

by the applicant's registered nurse employees who are trained through Pentec's certified nursing education program (*a copy of the program was provided in the attachment for Question 5.B of Supplemental 1*).

As noted, the infusion product will be compounded, packaged and shipped from the applicant's licensed pharmacy in Boothwyn, Pennsylvania and delivered by a Pentec driver or Federal Express to the assigned Pentec nurse. In some instances the product may be shipped to the patient's home where it will be received, inspected and authenticated by Pentec's nurse employee prior to administration. Types of infusion products to be administered include refills of intrathecal pump pain medications under physician orders for patients with cancer pain, multiple sclerosis or cerebral palsy and medications for patients receiving Ig-G replacement therapy.

Note to Agency Members: the above is a brief summary of the nature and scope of the proposed in-home skilled nursing service for infusion therapy patients. For more detailed descriptions about the nature and scope of services, including measures taken to reduce the risks associated with these types of patients, please see the HSDA staff questions for Item 4.A - 4.H on pages 6-15 of Supplemental 1 and the TDH questions in Exhibit 2 on pages 29-46 of Supplemental 2.

A description of the types of patients with demonstrated needs for infusion nursing services in the home that may otherwise be unavailable from other home health agencies include the following:

- **Implanted Intrathecal Pump Infusion Therapy** - this highly specialized service is given to a very narrow and complex range of patients who have failed traditional therapy for severe or chronic pain and now rely on implanted drug delivery systems for their treatment. Types of patient conditions include pain secondary to cancer, multiple sclerosis, traumatic brain injury, head trauma, paralysis or stroke. Carefully selected by their physicians, these patients will have a specialized pump implanted in the intrathecal space surrounding the spinal cord during a surgical procedure in an inpatient or outpatient setting and their medication regimen started. Implanted pump infusion therapy may be appropriate for patients who have the care and resources available to manage potential risks such as infection, narcotic withdrawal, drug compounding errors and pump programming errors. Typical patient diagnoses include Chronic Pain Syndrome, Complex Regional Pain Syndrome, Multiple Sclerosis, Cerebral Palsy, Abnormal Involuntary Movement (Spasticity) and Traumatic Brain Injury. (*For further detail regarding the ICD-9 codes that apply to these patients please see page 9, Supplemental 2*).

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- **Specialty Patients Requiring Ig-G Replacement Therapy** - Intravenous immunoglobulin, a fraction of blood containing antibodies, is given intravenously or by subcutaneous infusion as a plasma protein replacement therapy to immune and/or auto-immune deficient patients who cannot replace antibodies naturally. The frequency of Ig-G Replacement Therapy is different for 2 types of patients - (1) those with primary immune deficiency, a genetic disorder that typically requires lifetime treatment on a monthly basis; or (2) patients with auto immune deficiency that may require lifetime treatment but more typically have a treatment regimen consisting of three, six or twelve month segments in consecutive daily sessions of several hours per session. Typical patient diagnoses include Primary Immune Deficiency and Auto Immune Disorder.

Ownership

The applicant is a Pennsylvania Corporation first formed in 1983 under the name Delaware Valley Home Care Corporation and was later changed to Pentec Health Inc. in September 2006. It is a wholly owned subsidiary of Pentec Holdings, Inc. a Delaware Corporation, which has as its ultimate parent, Pentec Healthcare Infusions, Inc., also a Delaware Corporation. Related information about the applicant is provided below.

- The parent has 4 members with 5% ownership interest or greater, including Norwest Equity Partners IX, LP (69.06%), Norwest Mezzanine partners III, LP (5.06%), DW Healthcare Partners, LP (10.12%) and Frazier Healthcare V, LP (10.12%). Please see the table and chart on pages 101 and 102 of the application.
- The applicant has 2 major operating divisions - Specialty Infusion (includes home health care), and Renal Nutrition.
- The 2 operating divisions are supported by other operating units such as pharmacy, nursing, information services, quality assurance.
- An executive level organizational chart is provided on page 7 of Supplemental 2.
- As noted, Pentec operates a closed door specialty pharmacy with locations in Boothwyn, Pennsylvania and Mansfield, Massachusetts. The pharmacy is licensed in 50 states and supports the prescriptive needs of its intrathecal pump, infusion therapy and renal nutrition patients.
- The Tennessee pharmacy currently only focuses on the supply of renal nutrition products for use by Tennessee residents. It was first licensed in December 2004 (recently renewed through 3/31/2016). The applicant clarified that its pharmacy has the ability, capacity and trained staff to also prepare and supply intrathecal and intravenous compounded products (*please see page 4, Supplemental 2*).

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- A table on pages 16 and 17 of Supplemental 1 provides a list of Pentec Health, Inc.'s active pharmacy and home health services for each of the 50 states and District of Columbia.
- Pentec has an active home health agency license in 34 states. It is also pending licensure approval in New Mexico, New York and the District of Columbia.
- The fiscal year end intrathecal pump patient census of Pentec's Infusion Division grew by approximately 67% from 1,303 patients ending December 31, 2011 to 2,177 patients ending December 31, 2013.
- As addressed in the TDH summary, the applicant provided a copy of a \$10,000 civil penalty notice and order dated 08/22/2011 from the Indiana State Department of Health for violation of a licensure requirement during the applicant's initial state licensure survey.
- Also provided was copy of a 10/17/2011 letter from the program manager of the Acute Care Division, Indiana State Department of Health indicating that the plan of correction was found to be acceptable.

Facility Information

- The parent office of the proposed project will be in approximately 87 square feet of leased space in an existing office building in downtown Nashville at 424 Church Street.
- The office will be used solely for administrative support purposes as a repository for home health service policies and procedures, personnel records and other required documentation.
- There is no construction, renovation or modification required to implement the proposed project.
- Per Item 6, page 20 of Supplemental 1, branch offices would not be considered unless required with regional licensure requirements. The applicant attributes the nature of its specialized but limited service, its patient scheduling (7 to 10 day in advance of targeted pump refill or "alarm" date) and its nursing staffing plan as key factors in this regard.

Project Need

- The applicant indicates that traditional home health agencies do not typically provide in-home skilled nursing care for patients with surgically implanted intrathecal infusion pumps and patients receiving Ig-G replacement therapy.
- The nature of the proposed service differs from traditional home health agencies. The applicant provided a comparison in the table below.

Comparison of Applicant to Other Types of Home Health Agencies

Variable	Medicare Home Health Agency	Infusion Nursing Agency	Pentec Intrathecal Pump Service
Average Visit Duration	One to Two Hours	Up to six hours	One to Two Hours*
Equipment	Generally not involved	Typically includes infusion equipment	Administration kit (syringes & other disposable items) Pump programmer
Payor	80% Medicare and TennCare Patients	Private Insurance mainly	Mostly private insurance
Age	Approximately 68% Over Age 65+	Majority under Age 65	Approximately 71% under age 65
Service Provided	44% is skilled nursing. Additional services may include therapy, home health aide, and medical social services.	100% specialized skilled nursing	100% specialized skilled nursing
Patient Status	Homebound	Patient may or may not be homebound	May or may not be homebound

**Note: while duration of the visit is comparable, the applicant states that skilled nursing visits occur less frequently – approximately every 30- 60 days.*

- Patients may qualify for intrathecal pump therapy only when all other attempts for relief by the patient's physician have failed.
- Limited supply of physicians with practice specialties in pain management.
- Difficulty by patients to travel to physician for pump refills and office visits, especially patients with limited mobility or who are homebound.
- Discharged hospital patients requiring infusion nursing services either have to travel to the hospital or other outpatient facilities such as physician offices or infusion therapy centers to continue receiving this service.
- Need for accurate, reliable and timely information systems support to maintain patient medical record and facilitate communication with physicians through secure means. Pentec's electronic medical record system and secure web portal for attending physicians appears to be innovative initiatives in addressing this need.

- *Note to Agency members: The attachment to the Department of Health Report indicated that based on 2013 data, 102,200 service area residents will need home health care in 2018; however 182,973 patients are projected to be served in 2018 resulting in a net excess of (80,773). Please note that this need is calculated for all home health patients, not just those needing home infusion services.*

Service Area Demographics

- The proposed service area was revised from 95 to 92 counties during initial review based on publication in newspapers that did not meet the requirements for "newspapers of general circulation" in accordance with HSDA Rules. Per the TDH project summary, the total population of the 92 county statewide service area is estimated at 6,629,335 residents in calendar year (CY) 2015 increasing by approximately 3.7% to 6,874,743 residents in CY 2019.
- The population of the 3 counties not included in the service area (Hancock, Perry and Van Buren Counties) is estimated at approximately 20,103 residents in 2015 increasing by 0.08% to 20,254 residents in 2019.
- The overall statewide population is projected to grow by 3.7% from 2015 to 2019.
- The 65 and under population will increase by approximately 12% from 1,008,671 in 2015 to 1,129,890 in 2018. The statewide 65 and under population will increase by approximately 12% between 2015 and 2019.
- The latest 2014 percentage of the statewide population enrolled in the TennCare program is approximately 18.1%.

Sources: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics, U.S. Census Bureau, Bureau of TennCare.

Service Area Historical Utilization

Using licensure and provider utilization records maintained by the Tennessee Department of Health, the applicant identified approximately 157 existing licensed home health agencies in Tennessee. The name of the agency, location of parent office, licensed counties and utilization for 2011 – 2013 is provided in the table on pages 22-26 of Supplemental 1. As a whole, the agencies served approximately 176,910 patients in 2011 decreasing by 0.5% to 175,924 patients in 2013. Utilization for the 3 counties that were excluded from the applicant's proposed service area (Hancock, Perry and Van Buren Counties) increased slightly from 1,168 patients to 1,180 patients during the period.

Note to Agency members: The Joint Annual Report does not capture utilization data specific to implanted intrathecal pump or Ig-G replacement therapy

patients. There is not a known public database available that reports this type of data.

During review in 2012 of a previous Certificate of Need application for home infusion nursing (Coram Alternative Site Services), HSDA staff contacted the Tennessee Association of Home Care (TAHC) regarding home health providers and the Tennessee Hospital Association (THA) regarding hospital-based home care providers.

TAHC indicated the following:

- *TAHC membership applications on file indicate that 224 home health offices (parents and branches) offer infusion therapy services.*
- *Standard home health policy is that first dose should be completed in the hospital setting.*
- *The majority of home health agencies partner with an infusion company for administration of the second dose in the home.*
- *The home health nurse continues to support the patient's needs with observations and reports to the physician. It is unrealistic to think that a home health provider could limit their care to only infusion therapy. Infusion may be the primary need but these are typically patients with multiple chronic illnesses and co-morbidities who need a holistic, multi-disciplinary approach to their health care*
- *The barriers to home infusion therapy are generally noted as staffing and adequate payment. This is a growing issue for all homecare providers as both governmental and commercial payors continue to look to provider payments to cut costs.*
- *Homebound status is only a Medicare issue. An infusion company would be held to the same standard if it were a Medicare-certified home health agency.*

THA's response included that a "typical" home care provider does not provide infusion administration for:

- *Patients requiring 6 hour therapies.*
- *Medicare patients who are not homebound which is a requirement that applies only to Medicare.*
- *Many non-Medicare patients who are not homebound are served*
- *Patients requiring first dose administration*
- *Patients requiring three doses daily*

THA also advised that member home health agencies see patients in every county in the state and that there are pediatric programs often affiliated with

pediatric hospitals such as Vanderbilt, Methodist LeBonheur, and East Tennessee Children's Hospital.

During review of this application and 2 Coram/CVS Certificate of Need projects for specialty infusion services (please see descriptions for CN1406-017A and CN1406-018A at the end of this summary), HSDA staff received confirmation by phone and by an email from a representative of TAHC that the TAHC information provided in 2012 was still accurate at the time the applicant's proposal was under review in 2014.

Applicant's Projected Utilization

- In Year 1 the applicant projects an average daily census (ADC) of 20 patients per day increasing to 52 patients per day in Year 2 (*note: the applicant states that projected utilization focuses solely on intrathecal pump patients*).
- The applicant is projecting 121 total visits in Year 1 increasing to approximately 314 visits in Year 2. The applicant bases the projected intrathecal pump patient visit schedule on approximately 6 skilled nursing visits per patient per year.
- Year 1 projected utilization amounts to approximately 6.0% of the estimated 1,976 intrathecal pump patients in Tennessee in CY2014.
- Utilization for Year 1 is based on ramp-up of Pentec operations in Tennessee – beginning with 5 patients in the first month of operations going forward to 39 patients at year end.
- Of the 39 patients at year end, 20 are commercially insured and 19 are partial-reimbursement patients where Pentec receives compensation for some services rendered (usually medications) but assumes the patient's nursing care as a financial loss in accordance with its Compassionate Care policy. (*Sources: Application, page 36 and Supplemental 1, page 39*).
- Per the table on page 32 of Supplemental 1, the distribution of patients by **Grand Division of Tennessee** at the end of Year 1 is as follows: East (17), Middle (14) and West (8).

Project Cost

Major costs of the \$142,028 total estimated project cost are:

- Architectural and Engineering Fee- \$28,500 or 20% of total cost
- Office Lease- \$8,028 or 5.7% of total cost
- Reserve/Contingency Fund-\$100,000 or 70.4% of total cost

For other details on Project Cost, see the Project Cost Chart on page 40 of the application.

Historical Data Chart

- The applicant provided a historical data chart on page 44 of the application for their existing renal and specialty infusion division operations that are active in 30 states of the country. Pentec realized favorable net operating income of \$8,458,000 in 2011 decreasing to (\$41,262,000) in 2012 and (2,857,000) in 2013.
- As clarified by the applicant on page 39 of Supplemental 1, the negative amounts on line D.4 in the Historical Data Chart are based on tax benefits related to Pentec's net losses in 2012 and 2013.
- Review of the Consolidated Statements of Operations and the notes by the auditor on pages 9, 14 and 15 of audited financial statements confirmed the 2012 and 2013 net losses resulting from what appears to be a \$46,482,000 accounting assessment in fiscal year 2012 for "Impairment of Goodwill and Trade names". As noted, the assessment appears to be based on an estimated reduction in Medicare Part D reimbursement rates for renal nutrition services provided by Pentec during the period.
- The applicant states that it expects a favorable net income of \$4.2 million for the fiscal period ending December 31, 2014 (*please see page 51 of the revised application for more details*).

Projected Data Chart

The financial performance of the project appears to be favorable as proceeds from operating revenues cover operational costs. Highlights from the Projected Data Chart on page 46 of the revised application and the proformas on pages 123-125 in the attachments are as follows:

- Projected gross operating revenue increases from \$304,573 on approximately 121 patient visits (approximately \$2,517 per visit) to \$853,923 on 314 visits in Year 2 (approximately \$2,737 per visit).
- Net operating income is estimated at a loss of -\$1,251 in Year One improving to a favorable margin of \$117,812 in Year 2.
- Projected NOI calculates to approximately 13.8% of gross operating revenue in Year 2.
- Deductions from operating revenue consist entirely of bad debt estimated at \$19,797 increasing to \$55,505 in Year 2.
- As noted on page 39 of Supplemental 1 and pages 22 and 24 of Supplemental 2, Pentec's financial statements treat gross revenue as "net patient services operating revenue" and do not record charity care or contractual adjustments, although these amounts are taken into consideration.
- The applicant expects to provide charity care to one patient in Year 1.

Charges

In Year One of the proposed project, the average charge per visit is as follows:

- The proposed average gross charge is \$2,517.00 per intrathecal pump patient visit.
- The average deduction for bad debt is \$164.00 per patient visit, producing an average net charge of \$2,353.00 per patient visit.
- The applicant's expected gross charge per visit in Year 2 is expected to be \$2,720 per visit.
- The applicant provided an infusion therapy services fee schedule on page 157 of the revised application.
- The schedule includes charges that consist of the following general categories – per diem, drugs, nursing, supplies and other. As a cross reference, these categories are also reflected in the proforma on page 123 of the application and in the tables on page 21 of Supplemental 2.
- The applicant bases its projected charges on Pentec's infusion therapy operations experience in other states. Per clarification provided on page 41 of Supplemental 1, Pentec's typical reimbursement by commercial plans such as those shown on page 57 of the application averages approximately \$92 per visit for visits up to 2 hours and \$50-\$70 per day for per diem charges.

Medicare/TennCare Payor Mix

The applicant is only certified by Medicare and Medicaid as a pharmacy and durable medical equipment (DME) provider and will not seek Medicare and TennCare certification for the proposed specialty infusion home health agency.

- Even if the applicant wanted to apply for Medicare/TennCare, it may not be eligible since its services are limited to the provision of skilled nursing specialty infusion therapy services. The proposed limited scope of service would not be providing the full range of home health services prescribed by the Medicare Conditions of Participation.
- The applicant states that fee for service Medicare/TennCare would only cover drugs dispensed by its existing licensed Tennessee pharmacy for patients of the proposed agency. They would not cover skilled nursing services to administer them or manage patient conditions (*please see page 52 of the application*).
- While it will not seek Medicare/TennCare certification, Pentec maintains that it will accept traditional fee for service patients of these programs on a limited, compassionate care basis in accordance with existing corporate policies (*source: page 4, Supplemental 1*).
- The applicant's projected payor mix is 86% commercial insurance, 7% Medicare and 7% TennCare in Year 1.

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Financing

The project will be funded from cash reserves. Per Mr. Art Rea, Chief Financial Officer of Pentec Health, Inc., Pentec had cash on hand of approximately \$7.5 million as of October 31, 2014.

Review of Pentec's audited financial statements submitted with the revised application confirmed the availability of cash reserves to fund the \$142,028 proposed project. Per the Consolidated Balance Sheet, there was \$3,867,673 in cash for the 12-month period ending December 31, 2013. In addition, Pentec reported total current assets of \$20,785,836, total current liabilities of \$15,562,693 resulting in a current ratio of 1.34 to 1.0.

Note to Agency Members: Current Ratio is a measure of liquidity and is the ratio of current assets to current liabilities which measures the ability of an entity to cover its current liabilities with its existing current assets. A ratio of 1:1 would be required to have the minimum amount of assets needed to cover current liabilities.

Staffing

The applicant plans to use a 40 to 1 patient to nurse staffing ratio for the proposed agency. However, the applicant expects to staff one full time equivalent (FTE) licensed nurse in Year 1 despite the lower projected patient census that is expected for the first full year of the project. In addition, the applicant has allocated a 0.2 FTE Pentec Regional Nurse Manager to the project consistent with its practice in other states.

Licensure/Accreditation

If approved, the proposed Pentec Health, Inc. home health agency will be licensed by the Tennessee Department of Health.

- The applicant provided information regarding the licensing and accreditation of all of its existing home health and pharmacy sites, including its licensed Tennessee pharmacy, on pages 16 and 17 of Supplemental 1. A copy of the Tennessee pharmacy license is found on page 159 of the application.
- As noted, a letter dated October 17, 2011 from the Indiana State Department of Health states that the plan of correction in response to its 8/10/2011 initial state licensure survey was acceptable.
- A copy of Pentec Health Inc.'s 3-year Joint Commission accreditation award effective June 7, 2014 for the Home Health Accreditation Program with copy of applicable sites is shown on pages 162-165 of the application.

Corporate documentation, copies of the office lease and copies of corporate policies and procedures, including Infection Control, Pharmacy Quality Assurance and Pentec's

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Performance Improvement Plan are on file at the Agency office and will be available at the Agency meeting.

Should the Agency vote to approve this project, the CON would expire in two years.

Note to Agency members: Should the Agency choose to approve this application, Staff recommends the Agency limit any future expansion of services by requiring a new application to expand services beyond implanted intrathecal pump infusion services and Ig-G replacement therapy services rather than a modification request through the General Counsel's Report. This could be accomplished with the following condition:

Home Health Agency services are limited to specialized skilled nursing services under physician ordered plans of care for (1) patients with surgically implanted intrathecal pumps and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion. The expansion of services beyond the home infusion services described in the application will require the filing of a new certificate of need application.

CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT

There are no other Letters of Intent, denied or pending applications, or outstanding Certificates of Need for this applicant.

CERTIFICATE OF NEED INFORMATION FOR OTHER SERVICE AREA FACILITIES:

There are no other Letters of Intent for other health care organizations in the service area proposing this type of service.

Pending Applications

Implanted Pump Management, CN1407-027, has a pending application that will be heard under simultaneous review with CN1411-046 at the HSDA meeting on March 25, 2015 for the establishment of a home health agency to service intrathecal pump services to patients across all 95 counties in the State of Tennessee. The estimated project cost is \$275,000.

The Home Option by Harden Healthcare, CN1501-001, has a pending application that will be heard under CONSENT CALENDAR REVIEW at the March 25, 2015 Agency meeting for the initiation of home health services in

PENTEC HEALTH, INC.

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Blount, Campbell, Claiborne, Grainger, Monroe, Morgan, Roane and Scott Counties focusing on home health services to eligible individuals covered under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA), United States Department of Labor. If approved, the applicant's sister agency, Gentiva Certified Healthcare Corporation, will de-license the same 8 counties. The Home Health Option by Harden is located at 800 Oak Ridge Turnpike, Suite A208, Oak Ridge (Anderson County), TN 37830 and is currently licensed in Anderson, Jefferson, Knox, Loudon, Sevier and Union Counties. The estimated project cost is \$38,000.00.

Denied Applications:

Home Care Agency of Middle Tennessee, CN1001-001D, was denied at the June 23, 2010 Agency meeting for the establishment of a home care organization focusing on a full range of home health services and skilled nursing psychiatric services for the elderly population in a four (4) county service area including Davidson, Rutherford, Sumner, and Williamson Counties from a parent office located at 5115 Maryland Way, Brentwood, (Williamson County), Tennessee. The estimated project cost was \$69,000.00. *Reasons for Denial: There is not a need as there are other agencies in the proposed service area that are providing home health services, including services to the mentally ill, and it is not economically feasible to have another agency. The project will not contribute to the orderly development of adequate and effective health care.*

Rainbow Home Health, CN1111-045D, was denied at the February 22, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services, including skilled nursing, physical/occupational/speech therapies, and medical social services for individuals residing in Cheatham County from a home office located at 112 Frey Street in Ashland City (Cheatham County), Tennessee 37015. The estimated cost was \$262,600.00. *Reasons for Denial: the prevailing reason for the vote leading to the denial of the project (4 ayes, 6 nays, 0 ties) was based on concerns with nature and scope of information provided by the applicant that did not support the need for the project, the economic feasibility or the orderly development of the project.*

Rainbow Home Health, CN1203-013D, was denied at the June 27, 2012 Agency meeting for the establishment of a home care organization and the initiation of a full range of home health services from a home office located at 112 Frey Street, Ashland City (Cheatham County), Tennessee. The estimated project cost was \$27,950.00. *Reasons for Denial: the application was denied by unanimous vote based on the following: there was no need due to services being adequately provided by existing licensed agencies in the service area; the project was not economically feasible due to the*

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numbers not being justified or showing how the applicant could feasibly provide the service; and the project did not contribute to orderly development as it will impact the utilization and staffing of existing agencies in the service area.

Critical Nurse Staffing, CN1210-049D, was denied at the January 23, 2013 Agency meeting for the establishment of a home care organization located at 575 Oak Ridge Turnpike, Oak Ridge (Anderson County), Tennessee focusing on individuals eligible for benefits under either the Energy Employees Occupational Illness Compensation Program Act or the Federal Black Lung program that reside in Anderson, Campbell, Knox, Loudon, Monroe, Morgan, Roane, and Union Counties. The estimated project cost was **\$155,937.00**. *Reasons for Denial: There was no real need - care was being adequately provided by other agencies in the proposed service area and adequate evidence did not support or prove that there was a need for the proposed agency.*

Love Ones, CN1309-033D was denied at the February 26, 2014 Agency meeting for the establishment of a home health agency and initiation of home health services in Shelby, Fayette, and Tipton Counties. The parent office was to be located at 2502 Mount Moriah, Suite A-148, Memphis (Shelby County), TN 38116. The estimated project cost was **\$177,800.00**. *Reasons for Denial: The need for the proposed agency was not supported in this particular area as there are existing providers that have testified that they can accommodate a greater need than the actual patient census that they have proposed in the first two years of their business plan; Economic Feasibility - the project is not financially feasible considering the small number of patients, and they have underestimated the costs of what it is going to take to run a Medicare-certified agency.*

Outstanding Certificates of Need:

Coram Alternate Site Services, Inc. d/b/a Coram Specialty Infusion Services CN1406-018A has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization and the initiation of home health services limited to the provision and administration of home infusion products and related services ancillary to its pharmacy services in a 25 county service area of West Tennessee, including the following counties: Benton, Carroll, Chester, Crockett, Decatur, Dyer, Fayette, Gibson, Hardeman, Hardin, Haywood, Henderson, Henry, Houston, Lake, Lauderdale, McNairy, Madison, Obion, Perry, Shelby, Stewart, Tipton, Wayne and Weakley Counties. The parent office will be located in its licensed home infusion pharmacy at 1680 Century Center Parkway, Suite 12, Memphis, Tennessee, 38134. The estimated project cost is **\$98,000.00**. *Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram,*

PENTEC HEALTH, INC.

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the licensure application has been submitted to the Tennessee Department of Health. The initial licensing inspection for the parent office in Memphis, TN has been scheduled for March 13, 2015. An Annual Project Report is due on or before July 1, 2015.

Coram Alternative Site Services, Inc. d/b/a Coram Specialty Infusion Services, CN1406-017A, has a Certificate of Need that will expire on November 1, 2016. The project was approved at the September 24, 2014 Agency meeting for the establishment of a home care organization to provide the following specialized home health services related to home infusion: administer home infusion products and related infusion nursing services, by way of example and not limitation, line maintenance, infusion equipment repair and replacement, and dressing changes on central lines and external access ports. The proposed service area includes the following Tennessee counties: Anderson, Blount, Bradley, Campbell, Carter, Claiborne, Cocke, Fentress, Grainger, Greene, Hamblen, Hancock, Hawkins, Jefferson, Johnson, Knox, Loudon, McMinn, Meigs, Monroe, Morgan, Pickett, Polk, Roane, Scott, Sevier, Sullivan, Unicoi, Union, and Washington Counties, from its licensed home infusion pharmacy which will be located at 10932 Murdock Drive, Suite 101A, Knoxville (Knox County), TN 37932. The estimated project cost is \$95,200.00. *Project Status Update: per a 2/23/15 e-mail from legal counsel for Coram, the licensure application has been submitted to the Tennessee Department of Health. Notice of the inspection date is pending. An Annual Project Report is due on or before July 1, 2015.*

Maxim Healthcare Services, CN1406-015A, has an outstanding Certificate of Need that will expire on October 1, 2016. The project was approved at the August 27, 2014 Agency meeting for the initiation of home health care services in a 5 county service area including Carter, Johnson, Sullivan, Unicoi, and Washington Counties focusing primarily on private duty hourly care to TennCare medically complex pediatric patients. Maxim Healthcare Services seeks an unrestricted home health agency license and will obtain Medicare certification to meet TennCare provider enrollment requirements. The estimated project cost is \$463,825.00. *Project Status Update: per 2/27/15 e-mail from legal counsel for Maxim Health Care Services, the project was appealed but it appears that the parties have reached a settlement and the appeal may be dismissed in the near future. Confirmation of same will follow as soon as possible.*

Hemophilia Preferred Care of Memphis, CN1202-002, has an outstanding certificate of need that will expire on August 1, 2015. The CON was approved at the June 27, 2012 agency meeting for the establishment of a home health agency and the initiation of home health services limited to patients suffering from hemophilia or similar blood disorders who are patients of the pharmacy operated by Hemophilia Preferred Care of Memphis. The estimated project cost

PENTEC HEALTH, INC.

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is \$43,000. *Project Status: The applicant requested and received approval at the June 25, 2014 Agency meeting for a one year extension from August 1, 2014 to August 1, 2015.*

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF HEALTH, DIVISION OF HEALTH STATISTICS, FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PJG
03/04/2015

Letter of Intent



23

State of Tennessee
Health Services and Development Agency

Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

www.tn.gov/hsda

Phone: 615-741-2364

Fax: 615-741-9884

LETTER OF INTENT

The Publication of Intent is to be published in the The Tennessean (and others - see Attachment 1) which is a newspaper
(Name of Newspaper)
of general circulation in Davidson County (and others - see Attachment 1), Tennessee, on or before November 10, 2014,
(County) (Month / day) (Year)
for one day.

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency, that:

Pentec Health, Inc.

N/A

(Name of Applicant)

(Facility Type-Existing)

owned by: Pentech Holdings, Inc.

with an ownership type of Corporation

and to be managed by: Jamie Schultz, R.N.

intends to file an application for a Certificate of Need

for [PROJECT DESCRIPTION BEGINS HERE]: Establishment of a home care organization and initiation of home health services consisting of specialized

skilled nursing services provided under physician-ordered plans of care to (1) patients with implanted intrathecal pumps, and (2) patients receiving Immunoglobulin-G

replacement therapy through Intravenous or subcutaneous Infusion, in the patients' places of residence, in all 95 counties in the State of Tennessee. The organization

will serve the entire state from its office at 424 Church Street, Suite 2000, Nashville, TN 37219. The estimated project cost is \$142,000, including a \$100,000 reserve fund.

The anticipated date of filing the application is: November 14, 2014

The contact person for this project is Doug Wynd

National Sales Director, Specialty Infusion

(Contact Name)

(Title)

who may be reached at: Pentec Health, Inc.

4 Creek Parkway

(Company Name)

(Address)

Boothwyn

Pennsylvania

19061

636

/751-6481

(City)

(State)

(Zip Code)

(Area Code / Phone Number)

(Signature)

Nov. 03, 2014

(Date)

dwynd@pentechealth.com

(E-mail Address)

The Letter of Intent must be **filed in triplicate** and **received between the first and the tenth day of the month**. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

REVISED- COPY
-Application-
Pentec Health
Inc.

CN1411-046

SECTION A

APPLICANT PROFILE

PENTEC HEALTH, INC.

1. **Name of Facility, Agency, or Institution**

Pentec Health, Inc.

Name

424 Church Street, Suite 2000

Street or Route

Nashville

City

TN

State

Davidson

County

37219

Zip Code

2. **Contact Person Available for Responses to Questions**

Doug Wynd

Name

National Sales Director,
Specialty Infusion

Title

Pentec Health, Inc.

Company Name

dwynd@pentechealth.com

Email address

4 Creek Parkway

Street or Route

Boothwyn

City

PA

State

19061

Zip Code

Employee of Pentec Health, Inc.

Association with Owner

636-751-6481

Phone Number

610-494-6148

Fax Number

3. **Owner of the Facility, Agency or Institution**

Pentech Holdings, Inc.

Name

800-223-4376

Phone Number

4 Creek Parkway

Street or Route

Delaware

County

Boothwyn

City

PA

State

19061

Zip Code

(See Attachment, Section A, Applicant Profile, Item 3)

4. **Type of Ownership of Control (Check One)** (See Attachment, Section A, Applicant Profile, Item 4)

A. Sole Proprietorship

B. Partnership

C. Limited Partnership

D. Corporation (For Profit)

E. Corporation (Not-for-Profit)

☐
☐
☐
☒
☐
F. Government (State of TN or
Political Subdivision)

G. Joint Venture

H. Limited Liability Company

I. Other (Specify)

☐
☐
☐
☐
☐
☐
☐
☐

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

5. **Name of Management/Operating Entity (If Applicable)**

Not Applicable (N/A)

Name _____

Street or Route _____

County _____

City _____

State _____

Zip Code _____

**PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

6. **Legal Interest in the Site of the Institution (Check One)**

A. Ownership _____

D. Option to Lease _____

B. Option to Purchase _____

E. Other (Specify) _____

C. Lease of _____ Years _____

X

(See Attachment, Section A, Applicant Profile, Item 6)

**PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.**

7. **Type of Institution (Check as appropriate--more than one response may apply)**

A. Hospital (Specify) _____

I. Nursing Home _____

B. Ambulatory Surgical Treatment
Center (ASTC), Multi-Specialty _____

J. Outpatient Diagnostic Center _____

C. ASTC, Single Specialty _____

K. Recuperation Center _____

D. Home Health Agency _____

X

L. Rehabilitation Facility _____

E. Hospice _____

M. Residential Hospice _____

F. Mental Health Hospital _____

N. Non-Residential Methadone
Facility _____G. Mental Health Residential
Treatment Facility _____

O. Birthing Center _____

H. Mental Retardation Institutional
Habilitation Facility (ICF/MR) _____P. Other Outpatient Facility
(Specify) _____

Q. Other (Specify) _____

8. **Purpose of Review (Check) as appropriate--more than one response may apply)**

A. New Institution _____

X

G. Change in Bed Complement _____

B. Replacement/Existing Facility _____

[Please note the type of change
by underlining the appropriate
response: Increase, Decrease,
Designation, Distribution,
Conversion, Relocation]

C. Modification/Existing Facility _____

D. Initiation of Health Care Service
as defined in TCA § 68-11-
1607(4)
(Specify) _____

H. Change of Location _____

E. Discontinuance of OB Services _____

I. Other (Specify) _____

F. Acquisition of Equipment _____

9. **Bed Complement Data**
Please indicate current and proposed distribution and certification of facility beds.

	<u>Current Beds Licensed</u>	<u>*CON</u>	<u>Staffed Beds</u>	<u>Beds Proposed</u>	<u>TOTAL Beds at Completion</u>
A. Medical	_____	_____	_____	_____	_____
B. Surgical	_____	_____	_____	_____	_____
C. Long-Term Care Hospital	_____	_____	_____	_____	_____
D. Obstetrical	_____	_____	_____	_____	_____
E. ICU/CCU	_____	_____	_____	_____	_____
F. Neonatal	_____	_____	_____	_____	_____
G. Pediatric	_____	_____	_____	_____	_____
H. Adult Psychiatric	_____	_____	_____	_____	_____
I. Geriatric Psychiatric	_____	_____	_____	_____	_____
J. Child/Adolescent Psychiatric	_____	_____	_____	_____	_____
K. Rehabilitation	_____	_____	_____	_____	_____
L. Nursing Facility (non-Medicaid Certified)	_____	_____	_____	_____	_____
M. Nursing Facility Level 1 (Medicaid only)	_____	_____	_____	_____	_____
N. Nursing Facility Level 2 (Medicare only)	_____	_____	_____	_____	_____
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	_____	_____	_____	_____	_____
P. ICF/MR	_____	_____	_____	_____	_____
Q. Adult Chemical Dependency	_____	_____	_____	_____	_____
R. Child and Adolescent Chemical Dependency	_____	_____	_____	_____	_____
S. Swing Beds	_____	_____	_____	_____	_____
T. Mental Health Residential Treatment	_____	_____	_____	_____	_____
U. Residential Hospice	_____	_____	_____	_____	_____
TOTAL	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>	<u>N/A</u>

*CON-Beds approved but not yet in service

10. Medicare Provider Number 016727001 / 174583
 Certification Type 855S / 855B

11. Medicaid Provider Number 3950424 / 1512243
 Certification Type Pharmacy / DME

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid? No

13. **Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? No If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.**

Discuss any out-of-network relationships in place with MCOs/BHOs in the area.

A. 13. (continued)**1. Treatment of TennCare Participants**

As indicated in Section A, Applicant Profile, Item 12 of its application, Pentec Health, Inc. presently does not intend to seek Medicare or Medicaid certification for home health. Consequently, it has indicated in Section A.13 of the application that the project will not involve the treatment of TennCare participants.

Services to intrathecal pump patients are not covered under traditional Medicare and Medicaid coverage guidelines. However, Pentec accepts traditional fee-for-service Medicare and Medicaid patients on a limited, compassionate care basis. Pentec has developed a Compassionate Care Policy and a No Insurance Coverage Policy and has implemented these policies in all jurisdictions in which it operates. Approximately 3% of Pentec's total patient census is comprised of compassionate care patients for which no reimbursement is received. Additionally, approximately 61% of its total patient census is comprised of patients for which Pentec receives compensation for some services rendered, but not all. These patients are typically Medicare and Medicaid beneficiaries that do not have a home infusion benefit. In these cases, Pentec is usually reimbursed only for drugs administered and assumes the patient's nursing care at a financial loss. Pentec's budgeting process assumes that 25% of its total patient census will be treated pursuant to its Compassionate Care Policy, meaning that Pentec will receive either partial or no reimbursement. These policies would be implemented and followed by the HHA in Tennessee as elsewhere.

A. 13. (continued)**2. Relationships with Managed Care Organizations**

Pentec Health, Inc. has relationships with the following managed care organizations that have plan members located in Tennessee:

Contracted:

Humana, Inc.

Aetna, Inc.

WellPoint, Inc.

Blue Cross and Blue Shield of Alabama

Coventry Health and Life Insurance Company

Windsor Health Plan, Inc.

Independence Blue Cross

Blue Cross and Blue Shield of Nebraska

BlueCross BlueShield of Western New York

BlueShield of Northeastern New York

Blue Cross of Idaho Health Service, Inc.

Out of Network Billing Only:

BlueCross BlueShield of Tennessee

Cigna Corporation

UnitedHealthcare

Trustmark Companies

SummaCare Health Plan, Inc.

American Postal Workers Union Health Plan

Blue Cross Blue Shield of Michigan

U.S. Dept. of Health and Human Services, Pre-Existing Condition Insurance Plan

Blue Cross Blue Shield of North Dakota

Sterling Life Insurance Company

Blue Cross & Blue Shield of Rhode Island

GHI, an EmblemHealth Company

Transamerica Affinity Services

United Mine Workers of America

Alexian Brothers Community Services

CrestPoint Health

MVP Health Care

Providence Health Plan

SECTION B
PROJECT DESCRIPTION

PENTEC HEALTH, INC.

SECTION B: PROJECT DESCRIPTION

- I. **Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.**

1. Introduction

Pentec Health, Inc. ("Pentec") proposes to establish a specialized Home Health Agency ("HHA") in Tennessee to provide specialized nursing services primarily to patients with surgically-implanted medical devices called intrathecal pumps. Pentec may also provide immunoglobulin-G replacement therapy, through intravenous or subcutaneous infusion, as an ancillary service. All nursing services would be provided to patients in their places of residence, in all parts of the state, under physician-ordered plans of care. As a licensed pharmacy, Pentec will also serve its patients' prescriptive needs.

2. Pentec Health, Inc.

Pentec is a unique provider of specialty infusion therapy services to more than 2,250 patients in 30 states. It is accredited by The Joint Commission in both home care and pharmacy. Through its Specialty Infusion division, Pentec provides a limited, specialized home nursing service to complex patients suffering from severe pain or spasticity who have failed traditional therapy and now rely on implanted drug delivery systems for their treatment. These patients represent a narrow, complex and traditionally underserved population. Pentec serves these patients in their places of residence, on a 24/7 basis, with registered nurses who have completed Pentec's ANCC-certified training program. Pentec also operates a specialty closed-door pharmacy to fulfill its patients' prescriptive needs. Pentec is a Pennsylvania corporation that would be the HHA license holder and service provider in Tennessee.

3. Proposed Services

- A. *Intrathecal Pump Therapy*

An intrathecal pump is a complex medical device that delivers highly concentrated medication through a catheter directly into the intrathecal space surrounding the spinal cord. The pump is surgically implanted in an inpatient or outpatient facility (a procedure in which Pentec is not involved). Pump candidates must be selected carefully by physicians trained in interventional pain or spasticity management. These patients typically have been unable to obtain relief from traditional treatment for conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. The relief provided by the intrathecal pump can be significant, but this treatment is only appropriate for those who have the care and resources to manage the associated risks (such as infection, narcotics withdrawal, drug compounding errors, and pump programming errors). Consequently, these patients require access to highly specialized health services for the management, refill and nursing care associated with intrathecal pumps. Pentec is a national provider with the necessary experience, resources and expertise to provide this needed service cost-effectively.

Effective care of intrathecal pump patients requires both the ability to refill medications, which requires a pharmacy license, and the ability to administer medications, which requires skilled nursing services. Pentec's pharmacy staff is specially trained in the preparation of intrathecal drugs and required packaging and delivery systems, and the medication compounding occurs in an absolutely clean, controlled environment. Pentec is presently licensed in Tennessee as a pharmacy. Pentec proposes to provide the necessary nursing services with registered nurses licensed in Tennessee or a compact state. The nursing skills necessary to administer a patient's

medications and effectively monitor the operation of the delivery system are highly specialized. To ensure that its nurses have and maintain the required skills, Pentec has instituted a rigorous in-house program of classroom instruction, field training and proficiency evaluation. All Pentec nurses must successfully complete this program, which is the only such program certified by the American Nursing Credentialing Center (ANCC), and maintain required proficiency.

B. Immunoglobulin-G Replacement Therapy

As an ancillary service, Pentec proposes to provide immunoglobulin ("Ig-G") replacement therapy services to another limited patient population – those with compromised immune systems. Ig-G replacement therapy entails the administration, by IV or subcutaneous infusion, of immunoglobulin, a fraction of blood plasma containing antibodies, to replace antibodies that the patient cannot produce naturally. Ig-G replacement therapy is targeted at two groups: (1) those with primary immune deficiency, a genetic disorder that typically requires lifetime treatment on a monthly basis; and (2) those with auto immune deficiency, which may require lifetime treatment, but more typically is performed in 3-, 6- or 12-month therapy segments, in several consecutive daily sessions of several hours each. Provision of Ig-G replacement therapy would occur in the patient's residence under a physician-ordered plan of care.

4. Need for the Services

Pentec's proposal addresses an unmet health care need. Its in-home care model provides an underserved patient population with access to treatment that may otherwise be unavailable. Pentec treats patients at home because this delivery model improves access in a manner that is more cost-effective than the alternative, which requires patients to travel to a physician's office or a hospital for pump refills and maintenance. Because this area of medicine is so specialized, few physicians provide the service. Consequently, patients may be burdened with long travel times for treatment, or they may be unable to benefit simply because they lack access to proper care on an ongoing, regular basis. In-home delivery also enables physicians to offer this type of drug delivery to patients that may have been deemed too difficult to manage because of their condition or proximity to the physician's practice. Although some licensed HHAs may offer intrathecal pump services on a limited basis, no HHA with comparable experience, resources, technology and training programs is presently licensed in Tennessee.

5. Service Area and Staffing

Pentec's nursing team would be on call to serve patients located anywhere in Tennessee, 24 hours a day, 7 days a week. Patients will be able to reach their assigned nurse provider via a toll-free number, and calls made outside of office hours will be forwarded directly to Pentec's central call center, which in turn will contact the appropriate nursing team member. The nursing team is comprised entirely of registered nurses. The nursing team would be under the supervision of an HHA administrator, who in turn reports to Pentec's Vice President for Nursing Services, Karen McHenry, R.N., M.S.N., who has executive responsibility for all aspects of nursing services at Pentec.

6. Cost, Funding and Financial Feasibility

Pentec estimates that the cost to implement the project would be approximately \$42,000, which includes annual rent for its leased office, office equipment, administrative and legal fees, and application fees. In addition, Pentec has budgeted \$100,000 as a project reserve or contingency fund, although it does not presently anticipate use of this fund. The entire cost of the project will be funded through internally-generated cash. Pentec's financial projections for the project, which are based largely on its experience in the 10 states in which it has become licensed since 2011, indicate that the project will break even in 2015 (with a year-end patient census of 39) and be profitable in 2016 (with a year-end patient census of 63).

SECTION B: PROJECT DESCRIPTION**II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.**

- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project.**

If the project involves none of the above, describe the development of the proposal.

The project does not involve the construction, modification or renovation of a facility.

Pentec has leased an office in Nashville which will be used solely for administrative purposes and not for patient visits. The office is ready for occupancy, so no construction or renovation will be required. The office will be furnished for use by Pentec staff and will be used as a repository for HHA policies and procedures, personnel records, and other documentation required by Tennessee law. However, because patients would be treated in their places of residence by Pentec's highly mobile nursing team members, the office is not essential to the operation of the HHA.

Assuming issuance of the Certificate of Need and subsequent issuance of the HHA license, Pentec would implement project in Tennessee on a small scale, starting with an estimated 5 patients. It would increase the number of patients served by working with physicians in Tennessee with which it has established contacts, and by establishing new physician relationships. Pentec would implement the project with current registered nurse employees who are licensed to practice in Tennessee (or a compact state), who would serve as the initial HHA administrator and alternate administrator. Pentec would employ additional nurses locally as the need develops, based on its typical ratio of one nurse to every 40 patients. Because Pentec is able to manage staffing on a regional basis, it expects that utilization of its services in Tennessee would be close to 100%.

Pentec conservatively projects, for budgeting purposes, that its year-end patient census would be 39 in 2015 and 63 in 2016. However, proprietary commercial market research indicate that there are presently 1,976 intrathecal pump patients in Tennessee, so the number of potential patients is much greater than Pentec's financial projections indicate. In addition, Pentec estimates on the basis of population and the incidence of primary immune deficiency and auto immune deficiency diseases amongst the general populace, that the number of patients in need of Ig-G replacement therapy in Tennessee is approximately 1,020. These potential patients are not taken into effect in Pentec's projections. Pentec further estimates, on the basis of an analysis of intrathecal pump patient diagnosis codes, that approximately 10-15% of intrathecal pump patients also suffer from neuro-muscular disorders that may be treated by

Ig-G replacement therapy. In these cases, Pentec would be able to offer both types of treatment, which no other licensed provider would be able to do.

Pentec has invested heavily in technology, all of which will be available to the Tennessee HHA immediately upon implementation. This technology includes:

- a centralized call center that permits patients and their physicians to contact the responsible nursing team member 24 hours a day, 7 days a week;
- a proprietary, state-of-the-art electronic medical records ("EMR") system that allows access to patients' records from any location with internet service and is updated by Pentec's nurses in real time;
- a physician portal on Pentec's website that allows referring physicians and their staff to have secure 24/7 access to their patients' medical information that resides in the EMR system; permits secure, HIPAA-compliant, two-way electronic communications on items that require attention, like new prescriptions or plan of treatment changes; and provides physicians with immediate access to new information generated by Pentec's nurse during patient visits;
- a patient portal on Pentec's website that enables patients to have secure 24/7 access to their medical records, prescription information, medication schedule and pain or spasticity scores as measured against goals; and also permits secure, HIPAA-compliant communication with Pentec's nursing team; and
- secure, two-way videoconferencing that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the visit.

Pentec is already licensed in Tennessee as a pharmacy (Pharmacy License Number 4108, valid until February 28, 2015). Pentec owns and operates a closed-door specialty pharmacy to fulfill the prescriptive needs of its intrathecal pump patients, and its pharmacy staff is specially trained in the preparation of intrathecal drugs and required packaging and delivery systems. Therefore, in conjunction with the skilled nursing services that Pentec would provide to intrathecal pump patients, Pentec would also provide pharmacy services. Pentec's pharmacy would also have the ability to provide the medications administered to Ig-G replacement therapy patients. No additional investment would be required for Pentec's pharmacy to provide services in Tennessee.

- II. B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.**

Not applicable (NA). The proposed project does not involve patient beds.

SECTION B: PROJECT DESCRIPTION

II. C. As the applicant, describe your need to provide the following health care services (if applicable to this application):

1. **Adult Psychiatric Services**
2. **Alcohol and Drug Treatment for Adolescents (exceeding 28 days)**
3. **Birthing Center**
4. **Burn Units**
5. **Cardiac Catheterization Services**
6. **Child and Adolescent Psychiatric Services**
7. **Extracorporeal Lithotripsy**
8. **Home Health Services**
9. **Hospice Services**
10. **Residential Hospice**
11. **ICF/MR Services**
12. **Long-term Care Services**
13. **Magnetic Resonance Imaging (MRI)**
14. **Mental Health Residential Treatment**
15. **Neonatal Intensive Care Unit**
16. **Non-Residential Methadone Treatment Centers**
17. **Open Heart Surgery**
18. **Positron Emission Tomography**
19. **Radiation Therapy/Linear Accelerator**
20. **Rehabilitation Services**
21. **Swing Beds**

The only health care services on the list above that Pentec proposes to provide is home health services.

The services proposed by Pentec are substantially different from those typically offered by traditional home health agencies, which frequently offer a variety of skilled nursing services, and may offer other therapeutic services or home health aide services. By contrast, Pentec proposes to serve primarily patients with intrathecal pumps. These patients represent a very narrow, complex and traditionally underserved patient population for which there is limited support by traditional home health care and home infusion providers. Market research shows that there are presently 1,976 intrathecal pump patients in Tennessee.

Pentec's in-home patient care model provides a complex and underserved patient population with access to treatment that in many cases would not otherwise be available. Pentec delivers services to patients in their places of residence because this delivery model improves access to a service in a manner that is more cost-effective than the alternative, which requires patients to travel to a physician's office or a hospital for medication refills and pump maintenance. Because intrathecal medicine is so specialized, few physicians provide the service. Consequently, patients may be required to travel great distances for treatment (across state lines, in some cases), or they may be unable to benefit from intrathecal pump therapy simply because they lack access to proper care on an ongoing, regular basis. In-home delivery also enables physicians to offer this type of drug delivery to patients that may have been deemed too difficult to manage because of their condition or proximity to the physician's practice. At the present time, there are no licensed HHAs in Tennessee with the capability of providing intrathecal pump services on a statewide basis, so Pentec's proposal addresses an unmet health care need in Tennessee.

Although the proposed HHA would serve primarily intrathecal pump patients, Pentec would offer Ig-G replacement therapy as an ancillary service. Pentec estimates that approximately 1,020 Tennessee residents are in need of Ig-G replacement therapy, and that approximately 10-15% of intrathecal pump patients suffer from neuro-muscular disorders that are treatable by Ig-G replacement therapy. Pentec would be uniquely positioned to serve these "crossover" patients because no other licensed HHA is capable of providing both services.

SECTION B: PROJECT DESCRIPTION**II. D. Describe the need to change location or replace an existing facility.**

Not applicable (NA). The proposed project is new, so there is no change of location or facility replacement.

SECTION B: PROJECT DESCRIPTION

II. E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:

1. For fixed-site major medical equipment (not replacing existing equipment):

- a. Describe the new equipment, including:**
 - 1. Total cost (as defined by Agency Rule);**
 - 2. Expected useful life;**
 - 3. List of clinical applications to be provided; and**
 - 4. Documentation of FDA approval.**
- b. Provide current and proposed schedules of operations.**

Not applicable (NA). The proposed project involves no major medical equipment.

2. For mobile major medical equipment:

- a. List all sites that will be served;**
- b. Provide current and/or proposed schedule of operations;**
- c. Provide the lease or contract cost.**
- d. Provide the fair market value of the equipment; and**
- e. List the owner for the equipment.**

Not applicable (NA). The proposed project involves no major medical equipment.

3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of the lease and the anticipated lease payments.

Not applicable (NA). The proposed project involves no major medical equipment.

SECTION B: PROJECT DESCRIPTION**III. (A) Attach a copy of the plot plan of the site which must include:**

- 1. Size of site (in acres);**
- 2. Location of structure on the site;**
- 3. Location of the proposed construction; and**
- 4. Names of streets, roads or highway that cross or border the site.**

A site plan is attached as Attachment, Section B, Project Description, Item III (A).

Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. There will be no new construction or land development in connection with this project. A street plan indicating the location of the Fifth Third Center is attached in lieu of a plot plan.

1. The size of the site (Fifth Third Center) is approximately two acres.
2. The location of the structure on the site is indicated on the attached street plan.
3. Not applicable (NA).
4. The site is bordered by Church Street to the south, Fifth Avenue N. to the west, and Arcade Alley to the east.

SECTION B: PROJECT DESCRIPTION

- III. (B) Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/ clients.**

The office leased by Pentec is located in a modern, Class A office building that is handicap-accessible and ADA compliant. It is located in downtown Nashville, approximately one-quarter mile from U.S. Highways 41 and 70, and one mile from Interstate Highways 24, 40 and 65. The office is served by public transportation in the form of several city bus routes that stop at the intersection of Church Street and Fifth Avenue North.

Pentec's office will be used solely for administrative purposes, and not for patient visits. Nevertheless, the site is very accessible to all visitors for the reasons described above.

SECTION B: PROJECT DESCRIPTION**IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc.**

A floor plan is attached as Attachment, Section B, Project Description, Item IV.

Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. A floor plan of the office suite in which the office is located is attached. The Pentec office is number 2069 as indicated on the floor plan. Pentec and its visitors also have the use of the office suite common areas, including the Business Lounge, Refreshment Bar and restrooms, which are also depicted on the floor plan.

Pentec's office will be used for HHA administrative purposes only. Patients will not be examined or treated in the office.

SECTION B: PROJECT DESCRIPTION**V. For a Home Health Agency or Hospice, identify:**

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

1. Existing Service Area

Not applicable (NA). The proposed project is new.

2. Proposed Service Area

Pentec proposes to serve patients who reside in all 95 counties in the State of Tennessee, listed alphabetically as follows: Anderson, Bedford, Benton, Bledsoe, Blount, Bradley, Campbell, Cannon, Carroll, Carter, Cheatham, Chester, Claiborne, Clay, Cocke, Coffee, Crockett, Cumberland, Davidson, Decatur, DeKalb, Dickson, Dyer, Fayette, Fentress, Franklin, Gibson, Giles, Grainger, Greene, Grundy, Hamblen, Hamilton, Hancock, Hardeman, Hardin, Hawkins, Haywood, Henderson, Henry, Hickman, Houston, Humphreys, Jackson, Jefferson, Johnson, Knox, Lake, Lauderdale, Lawrence, Lewis, Lincoln, Loudon, McMinn, McNairy, Macon, Madison, Marion, Marshall, Maury, Meigs, Monroe, Montgomery, Moore, Morgan, Obion, Overton, Perry, Pickett, Polk, Putnam, Rhea, Roane, Robertson, Rutherford, Scott, Sequatchie, Sevier, Shelby, Smith, Stewart, Sullivan, Sumner, Tipton, Trousdale, Unicoi, Union, Van Buren, Warren, Washington, Wayne, Weakley, White, Williamson, and Wilson.

3. Parent or Primary Service Provider

Pentec would be the HHA license holder and service provider in Tennessee. All services would be provided by registered nurses.

4. Existing Branches

Not applicable (NA). The proposed project is new.

5. Proposed Branches

No branches are proposed. Pentec's proven patient care model would enable it to serve patients in their places of residence, at any time of day, anywhere in the State of Tennessee.

SECTION C

GENERAL CRITERIA FOR CERTIFICATE OF NEED

PENTEC HEALTH, INC.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

In accordance with Tennessee Code Annotated § 68-11-1609(b), "no Certificate of Need shall be granted unless the action proposed in the application for such Certificate is necessary to provide needed health care in the area to be served, can be economically accomplished and maintained, and will contribute to the orderly development of health care." The three (3) criteria are further defined in Agency Rule 0720-4-.01. Further standards for guidance are provided in the state health plan (Guidelines for Growth), developed pursuant to Tennessee Code Annotated §68-11-1625.

The following questions are listed according to the three (3) criteria: (I) Need, (II) Economic Feasibility, and (III) Contribution to the Orderly Development of Health Care. Please respond to each question and provide underlying assumptions, data sources, and methodologies when appropriate. All exhibits and tables must be attached to the end of the application in correct sequence identifying the question(s) to which they refer. If a question does not apply to your project, indicate "Not Applicable (NA)."

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

NEED

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

The HHA proposed by Pentec will contribute toward the achievement of each of the State Health Plan's Five Principles for Achieving Better Health. The Principles and the impact that implementation of the proposal will have on each Principle are stated and described below.

Principle 1: Healthy Lives – "The purpose of the State Health Plan is to improve the health of Tennesseans."

Pentec's proposal involves the establishment of an HHA that will provide very specialized services to two complex and underserved categories of patients in Tennessee: those with implanted intrathecal pumps, and those in need of immunoglobulin-G replacement therapy through IV or subcutaneous infusion. Both categories of patient may be considered chronically ill. The proposed services will improve the health of these patients.

Patients with intrathecal pumps typically suffer from conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. For these patients, many of whom have failed to find relief from more traditional treatments, the relief afforded by intrathecal pump therapy can be significant, and often they are able to resume many normal life activities as a result.

The estimated population of intrathecal pump patients in Tennessee is limited – about 1,976 persons at the present time. However, because relatively few physicians practice in this specialty, and because support by traditional home health agencies for these patients is very limited, many patients need to travel great distances to a physician's office or hospital for treatment. For most patients, this means a visit every 30 days, although in some cases the interval may be shorter or longer. For patients who are home-bound or suffer from limited mobility, this travel requirement can be burdensome. Moreover, a missed appointment due to travel-related problems could result in the patient's pump running dry – a potentially life-threatening situation that cannot be allowed to occur. Because Pentec provides services to its patients in their places of residence, and because its specially-trained nurses are available to treat patients 24/7, the proposed HHA will eliminate both the burden of travel on patients and the serious risks to patients that could result from failure to have the pump refilled on time. Although the patient population is small, the health benefits to the affected patients are substantial.

Other Tennesseans who suffer from conditions that are treatable with the intrathecal pump may be unable to benefit from the therapy simply because they lack access to proper care on an ongoing and regular basis. Pentec's in-home patient care model addresses this unmet need.

Pentec estimates that approximately 1,020 Tennesseans are presently in need of Ig-G replacement therapy. Recipients of Ig-G replacement therapy have compromised immune systems: either primary immune deficiency, which typically requires lifetime treatment on a monthly basis, or auto immune deficiency, which may require lifetime treatment, but more typically is performed in 3-, 6- or 12-month therapy segments. Because these patients cannot produce antibodies naturally, Ig-G replacement therapy is necessary to allow them to fight infectious disease and remain healthy.

Principle 2: Access to Care – “Every citizen should have reasonable access to health care.”

Intrathecal pump patients and Ig-G replacement therapy patients can be treated in a physician office or a hospital, but this may be burdensome to patients. Many intrathecal pump patients suffer from limited mobility and some are home-bound, while others (particularly those treated for spasticity) are juveniles. For these patients, travel requirements may make access more difficult or may preclude access entirely. For patients with auto immune deficiency, Ig-G replacement therapy is typically administered in 3-, 6- or 12-month therapy segments, in several consecutive daily sessions of several hours each. For these patients, travel for treatment can also be a burden. The proposed services will improve access to necessary care for both patient categories.

Because Pentec's proposal entails the establishment of a specialized HHA that would provide intrathecal pump therapy and Ig-G replacement therapy to patients in their places of residence only, barriers to access caused by patients' limited mobility or home-bound status, or by the need for transportation generally, would be eliminated. Moreover, because Pentec would treat patients in all 95 counties in Tennessee, its services would, by definition, be available to patients who live in all Medically Underserved Areas (MUAs) and Health Provider Shortage Areas (HPSAs) in the state. As a national provider of specialty home infusion services since 1983, Pentec has vast experience with the target patient populations (having had more than 100,000 patients on service) and is uniquely positioned to meet the needs of patients on an individual, case-by-case basis. Each Pentec patient is assigned to one “primary care nurse”, which facilitates development of a patient-provider relationship based on mutual trust and communication.

Pentec's proprietary technology would further enhance access to care by the subject patient population. This technology includes a centralized communication system that allows patients to reach their primary care nurse, 24 hours a day, 7 days a week; a patient portal on Pentec's website that enables patients to have secure 24/7 access to their medical records and permits secure, HIPAA-compliant communication with Pentec's nursing team; a physician portal that provides treating physicians secure 24/7 access to their patients' medical information and also allows secure, HIPAA-compliant communication with Pentec; and secure, two-way videoconferencing capability that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the in-home visit.

Principle 3: Economic Efficiencies – “The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's health care system.”

Implementation of the proposal by Pentec, an experienced national provider of specialty home infusion services, will introduce economic efficiencies by reducing costs to the health care system in the Tennessee.

First, because the proposed services will be provided to patients in their places of residence, there is strong potential for reduction of use of inpatient and outpatient care. The absence of licensed HHAs providing services to intrathecal pump patients in Tennessee means that these patients presently must travel to a physician's office or hospital for treatment. Pentec believes that reducing the volume of care provided in an office or hospital setting could result in significant health care system cost savings. Research has shown that the costs of care associated with intrathecal pump patients cared for in a traditional physician office setting varies considerably based on patient circumstances. Among patients with pain and spasticity, average annual health

plan expenditures are estimated to be \$70,000.¹ Over half of those expenses are for inpatient encounters that may have been averted by a more comprehensive care model such as that provided by Pentec. Research is ongoing to further define the costs of care in the usual care setting versus the Pentec in-home delivery model. However, evidence suggests that the reimbursable costs associated with refills of patients' pumps (medications and the procedure itself) are likely to be lower than the comparable reimbursable costs if the same service were provided by a physician in an office or hospital. Given that the typical patient may have 12 or more refills annually, these savings would accumulate over time.

Second, in emergency situations (caused, for example, by a pump running dry due to a missed appointment), patients may need to visit a hospital emergency department for care, and may need to use ambulance transportation. The proposed services, which would be available to patients in their homes on a 24/7 basis, reduce the incidence of patients' presenting at a hospital emergency department for treatment or using ambulances for transportation to a health care facility.

Delivery of Ig-G replacement therapy in patients' places or residence also has strong potential to reduce use of inpatient care (and to reduce the cost of care), for many of the same reasons described above with respect to intrathecal pump services. An added benefit of in-home care for immune-deficient patients is the reduced risk of hospital-acquired infection (often caused by more virulent and more antibiotic-resistant pathogens than infections that are community-acquired). Reduction of lost productivity (e.g., missed work by patients) due to infection represents an indirect benefit of in-home treatment. In addition, because hospitals typically treat Ig-G replacement patients during the work week, in-home treatment (which can occur on weekends or in the evening) may further reduce lost productivity due to missed work.

Principle 4: Quality of Care – "Every citizen should have the confidence that the quality of health care is continually monitored and standards are adhered to by health providers."

The services proposed by Pentec are **safe, effective, patient-centered, timely, efficient and equitable**.

First and foremost, Pentec has ensured through its rigorous nurse training and ongoing evaluation program that the services provided to patients are **safe**. Intrathecal pump patients require treatment on a regular and continuing basis, and this treatment must be provided by professionals with the required specialized skills. The specific needs of these patients involve primarily the management, refilling, reprogramming and nursing care associated with pumps and the medical conditions treated. Proper maintenance of the pump is essential due to heightened risk of infection and the consequences of pump malfunction. Once the pump is implanted, medication is administered continually into the spine, so the pump must be refilled with the prescribed medications and reprogrammed regularly. Because intrathecal drugs are highly concentrated and do not enter the patient's bloodstream, the side effects inherent with high-dose oral or IV narcotics and oral baclofen are greatly reduced. However, precise dosing is vital and must be carefully monitored. The health benefits to these patients can be substantial, but the associated risks mandate treatment by qualified and experienced health care professionals.

¹ Burden of Patients with Intrathecal Drug Delivery System – An Administrative Claims-Based Analysis, S.R. Palli, M. Abens, R. A. Quimbo, S. Fisher (2011). This study, which was funded by Pentec, was presented at the 15th Annual North American Neuromodulation Society (NANS) Meeting, Las Vegas, Nevada, December 8-11, 2011; and the full manuscript thereof has been accepted for publication by the peer-reviewed medical journal Neuromodulation.

The proposed services will be provided by specially-trained and certified registered nurses. Although all Pentec nurse providers are licensed as registered nurses by Tennessee or a compact state, they must complete special training to ensure that they have and maintain the skills required to administer patients' medications and monitor operation of the delivery system. This requires a rigorous program of classroom instruction, field training and ongoing proficiency evaluation by practitioners with expertise in treatment of intrathecal pump patients. Pentec's "Primary Care Nurse Training and Certification Program" is the only such program in the United States that has been certified by the American Nursing Credentialing Center (ANCC). In addition, after completion of the training program, Pentec nurses must maintain all required proficiencies on an ongoing basis. To accomplish this, Pentec's Lead Regional Nurse visits all nurses in the field at least annually to conduct an on-site performance evaluation. Pentec nurses must complete an annual evaluation of all applicable standards of performance, and must demonstrate continuing competence in all necessary procedures. Further, Pentec itself is accredited by The Joint Commission in both pharmacy and home care.

Pentec collaborates closely with referring physicians to ensure that therapy provided is **effective**. Because Pentec's patients are all referred by specialists in areas such as pain management, spasticity and neuromuscular disease, and because these patients have typically failed to find relief from alternative therapies, the likelihood that a patient would receive inappropriate or unnecessary therapy is minimized.

Pentec's model of care is **patient-centered** by design. Each patient is assigned to one primary care nurse, and Pentec maintains a low patient-nurse ratio of approximately 40:1. Pentec has developed over many years policies designed to ensure effective, regular communication between nurse, patient and treating physician; respect for patient preferences (e.g., advance directives); awareness of cultural sensitivities; and prompt response to complaints, amongst others. Pentec has invested heavily in technology that allows patients to communicate with their nurse providers anytime, anywhere.

The proposed services are **timely** by definition. Although treatment of patients is always scheduled in accordance with the patient's individual plan of treatment, it is accessible 24/7 and can be delivered anywhere in Tennessee.

As discussed under Principle 3, above, the proposed services are **efficient**. By eliminating unnecessary patient travel and reducing the incidence of inpatient and outpatient care, emergency department visits, and use of EMS, efficient delivery of health care is increased and costs are decreased.

Finally, the proposed services are **equitable**. The entire population of patients with intrathecal pumps is medically underserved at present. Because all intrathecal pump patients referred to Pentec have had their pumps surgically implanted prior to the start of service, Pentec does not have the ability to target specific sub-populations within the larger population of pump patients. However, for the company as a whole, approximately 56% of patients are women, and approximately 29% are age 65 or older. In addition, a significant portion of Pentec's patients may be considered handicapped to a degree, as a result of congenital conditions such as cerebral palsy, the progression of illnesses such as multiple sclerosis, or the occurrence of traumatic events such as stroke, head trauma, and spinal cord or brain injury. Finally, though its "Compassionate Care" policy, Pentec provides services to those without the ability to pay. Pentec's budgeting process assumes that 25% of the total patient census will be treated pursuant to its Compassionate Care policy, meaning that Pentec will receive either no reimbursement, or partial reimbursement, for services provided.

Principle 5: Health Care Workforce – “The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.”

Pentec will not only serve Tennesseans with a highly-qualified workforce from inception of the proposal, but it will also provide specialized training and certification to Tennessee nurses at its own expense.

In keeping with Pentec's usual practice, the proposal would be implemented by an administrator and alternate administrator, both registered nurses licensed to practice in Tennessee, both of whom are experienced Pentec employees. As the HHAs patient census increases, these nurses would be supplemented by local hires who would then undergo Pentec's ANCC-certified Primary Care Nurse Training and Certification Program. Eventually, these local employees would assume responsibility for administration of the HHA. In this manner, Pentec's proposal would enhance the quality of the health care workforce in Tennessee.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED**

- a. **Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.**

The criteria and standards applicable to "Home Health Services" are set forth below, together with Pentec's response to each.

1. *The need for home health agencies/services shall be determined on a county by county basis.*

Because the patients with intrathecal pumps and the population of patients in need of Ig-G replacement therapy are widely dispersed throughout the general population, Pentec proposes to serve these patients in all 95 counties in the State of Tennessee.

2. *In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county. The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.*

Not applicable (NA). Because of the limited and highly specialized nature of the proposed services, the general formula stated above does not provide an estimate of need for the services.

3. *Using recognized population sources, projections for four years into the future will be used.*

Not applicable (NA). Because of the limited and highly specialized nature of the proposed services, the rate of general population growth does not provide an estimate of need for the services.

4. *The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area. Based on the number of patients served by home health agencies in the service area, an estimation will be made as to how many patients could be served in the future.*

Not applicable (NA). Because of the limited and highly specialized nature of the proposed services, there is no comparable licensed HHA in Tennessee that could be used for purposes of utilization analysis.

5. *Documentation from referral sources:*

- a. *The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.*

(To be provided)

- b. *The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.*

Referrals of patients with intrathecal pumps are typically made by specialists who practice in the areas of interventional pain or spasticity management. These patients have been selected carefully by their treating physicians for intrathecal pump therapy, and their pumps have already been implanted at the start of service by Pentec. Pump patients typically have been unable to obtain relief from traditional treatment for conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. Although there are presently approximately 1,976 Tennesseans with intrathecal pumps, Pentec has conservatively projected for financial purposes that its patient census would be 39 at year-end 2015 and 63 at year-end 2016.

Referrals of patients for Ig-G replacement therapy are typically made by specialists in immune deficiency disease. Although Pentec estimates that approximately 1,020 Tennesseans are in need of Ig-G replacement therapy, Pentec has not taken any of these patients into effect for purposes of financial projections.

- c. *The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.*

(To be provided)

- d. *The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.*

As indicated throughout its application, Pentec proposes to provide a very specialized type of service that is limited to treatment of patients who have a surgically-implanted intrathecal pump and patients in need of immunoglobulin-G replacement therapy in their places of residence. This service can be categorized as a type of skilled nursing. However, unlike traditional home health agencies, Pentec would not provide other types of therapy services (such as physical, speech or occupational therapy) or home health aide or similar services. In addition, unlike several Tennessee home infusion providers that serve a small number of counties, Pentec would have the capability of providing, and proposes to provide, services to patients located anywhere in Tennessee on a 24/7 basis.

- 6. *The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.*

- a. *The average cost per visit by service category shall be listed.*

Pentec projects, on the basis of its experience nationally and the projected number of Tennessee patients, that the average billed cost per visit for intrathecal pump therapy patients in Tennessee, for the year 2015, would be \$2,471, which is the total of the following: drugs (\$588), nursing services (\$71), supplies (\$37) and per diem (\$1,775).

For Ig-G replacement therapy patients, the average billed cost per visit is \$9,810, which is the product of \$109/gram of Ig-G multiplied by 90 grams/visit.

- b. *The average cost per patient based upon the projected number of visits per patient shall be listed.*

The average treatment frequency for all intrathecal pump patients is 6 times per year. Therefore, the average annual cost per intrathecal pump patient, based on the average cost per visit stated above, would be \$14,826.

Assuming 6 visits per year, the annual cost for Ig-G replacement therapy patients is \$58,860.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED**

- b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c).**

Not applicable (NA). The proposed project is new, so there is no change of site.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED****2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.**

Implementation of the proposed services in Tennessee is consistent with Pentec's long-range goals.

First, by providing intrathecal pump therapy to patients who live in Tennessee, Pentec would be closing a significant gap its coverage area in the South, which presently includes the neighboring states of Kentucky, Virginia, North Carolina, Georgia, Alabama and Mississippi. Through its activities and provider relationships in these neighboring states, Pentec is aware of situations in which Tennessee residents with intrathecal pumps presently must travel out of state (e.g., from northwestern Tennessee to a provider in Paducah, Kentucky) due to unavailability of in-home service by licensed Tennessee HHAs.

Second, Pentec is in the process of expanding its Ig-G replacement therapy services in the mid-Atlantic region and the South. Provision of Ig-G replacement therapy services in Tennessee is consistent with this plan. Because these services are also being expanded in neighboring states, failure to provide them in Tennessee would again result in a coverage gap that Pentec desires to avoid.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED**

- 3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area.**

A map of proposed service area is attached as Attachment, Section C, Need, Item 3.

The proposed service area is all 95 counties in the State of Tennessee. This service area is reasonable for two reasons. First, it would expand access to needed health care services to a patient population that is presently underserved. Because intrathecal pump patients and Ig-G replacement therapy patients tend to be distributed evenly throughout the population, greater concentrations of these patients can be found in larger cities and metropolitan areas such as Memphis, Nashville, Chattanooga and Knoxville, and a provider of specialty home infusion services could capture a significant percentage of Tennessee's patient population while limiting its service area to a small number of counties. However, such a proposal would be contrary to the goals of improved access and equitable provision of services articulated in the State Health Plan, and it has never been Pentec's model in any jurisdiction.

Second, Pentec's proposed service area is reasonable because Pentec has the experience and resources to implement in-home care of intrathecal pump and Ig-G replacement therapy patients on a statewide basis. At present, Pentec provides specialty home infusion services in 30 states through use of its highly-mobile, specially-trained nursing teams. In every case, it provides these services to patients in all parts of the state except where restricted by conditions of licensure (e.g., Kentucky, where Pentec is licensed to serve 116 of 120 counties). Within the past four years, Pentec has obtained appropriate home health licenses and implemented statewide (or near-statewide) service in New Hampshire, Virginia, North Carolina, Indiana, Illinois, Kentucky, Minnesota, Nebraska, Colorado and Texas.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED****4. a. Describe the demographics of the population to be served by this proposal.**

As noted in the answer to Section C, Need, Item 1, intrathecal pump patients and Ig-G replacement therapy patients are widely distributed throughout the population in general. Moreover, Pentec does not track or otherwise classify its patients on the basis of race or ethnicity. However, for the company as a whole, approximately 56% of Pentec's patients are women, and approximately 29% are age 65 or older. Also, a significant percentage of Pentec's patients may be considered handicapped to some degree as a result of congenital conditions such as cerebral palsy, the progression of illnesses such as multiple sclerosis, or the occurrence of traumatic events such as stroke, head trauma, and spinal cord or brain injury.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED**

4. b. **Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.**

Because Pentec proposes to serve only patients with intrathecal pumps and patients in need of Ig-G replacement therapy, it is appropriate to consider the special needs of these populations specifically, rather than the general population in the service area.

As described in the answer to Section C, Need, Item 1, Pentec's target patient population may be considered chronically ill. Intrathecal pump patients typically suffer from chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer. These patients frequently have limited mobility and some may be home-bound. Ig-G replacement therapy patients suffer from primary immune deficiency or auto immune deficiency; they are incapable of producing antibodies to fight infection naturally. Both types of patients require continuing care, typically on a life-long basis. Intrathecal pump patients must have their pumps refilled and reprogrammed at periodic intervals – most typically every 30 days, but in some cases as often as every 10 days, or as infrequently as every 120 days. Patients with primary immune deficiency have a genetic disorder that typically requires lifetime treatment on a monthly basis, while those with auto immune deficiency most often are treated in 3-, 6- or 12-month therapy segments, in several consecutive daily sessions of several hours each.

For intrathecal pump patients, the frequency of treatment, relative lack of licensed in-home providers of intrathecal pump therapy, and limited number of physicians who practice in this area of medicine often means that inconvenient and burdensome travel for pump refills and reprogramming is necessary. This problem is compounded for the home-bound, those with limited mobility, the elderly and pediatric patients. As a consequence, many patients who could benefit from intrathecal pump therapy simply do not have access. Pentec's in-home patient care model is designed to address this fundamental access problem.

Services to intrathecal pump patients are not covered under traditional Medicare and Medicaid coverage guidelines. However, Pentec accepts traditional fee-for-service Medicare and Medicaid patients on a limited, compassionate care basis. Pentec has developed a Compassionate Care Policy and a No Insurance Coverage Policy and has implemented these policies in all jurisdictions in which it operates. Approximately 3% of Pentec's total patient census is comprised of compassionate care patients for which no reimbursement is received. Additionally, approximately 61% of its total patient census is comprised of patients for which Pentec receives compensation for some services rendered, but not all. These patients are typically Medicare and Medicaid beneficiaries that do not have a home infusion benefit. In these cases, Pentec is usually reimbursed only for drugs administered and assumes the patient's nursing care at a financial loss. Pentec's budgeting process assumes that 25% of its total patient census will be treated pursuant to its Compassionate Care Policy, meaning that Pentec will receive either partial or no reimbursement. These policies would be implemented and followed by the HHA in Tennessee as elsewhere.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED**

5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

At present, no licensed HHA provides both intrathecal pump therapy services and Ig-G replacement therapy services to patients in their places of residence on a 24/7 basis in all counties in the State of Tennessee. Consequently, no data are available for review.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**NEED**

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

The following documents are attached at Attachment, Section C, Need, Item 6:

1. Utilization and revenue data for Pentec Health, Inc. as a whole for the fiscal years ended December 31, 2011, 2012 and 2013; and projected utilization and revenue for the proposed Tennessee HHA for years 2015 and 2016.
2. Supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

- **All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)**
- **The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.**
- **The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.**
- **For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.**

The Project Cost Chart is included on the following page.

PROJECT COST CHART**A. Construction and equipment acquired by purchase:**

1.	Architectural and Engineering Fees	\$ 28,500
2.	Legal, Administrative (Excluding CON Filing Fee), Consultant Fees	
3.	Acquisition of Site	
4.	Preparation of Site	
5.	Construction Costs	
6.	Contingency Fund	
7.	Fixed Equipment (Not included in Construction Contract)	
8.	Moveable Equipment (List all equipment over \$50,000)	
9.	Other (Specify) <u>Miscellaneous office equipment</u>	\$ 2,500

B. Acquisition by gift, donation, or lease:

1.	Facility (inclusive of building and land)	
2.	Building only	
3.	Land only	
4.	Equipment (Specify) _____	
5.	Other (Specify) <u>Office lease (annual rent)</u>	\$ 8,028

C. Financing Costs and Fees:

1.	Interim Financing	
2.	Underwriting Costs	
3.	Reserve for One Year's Debt Service	
4.	Other (Specify) <u>Reserve / contingency fund</u>	\$100,000

**D. Estimated Project Cost
(A+B+C)**

\$139,028

E. CON Filing Fee

\$ 3,000

**F. Total Estimated Project Cost
(D+E)****TOTAL** \$142,028

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY****2. Identify the funding sources for this project.**

Please check the applicable item(s) below and briefly summarize how the project will be financed. (Documentation for the type of funding **MUST** be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)

- ☐ A. Commercial loan--Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds--Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds--Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants--Notification of intent form for grant application or notice of grant award; or
- ☒ E. Cash Reserves--Appropriate documentation from Chief Financial Officer.
- ☐ F. Other--Identify and document funding from all other sources.

The project will be funded entirely by means of cash reserves. As of December 31, 2013, on a consolidated basis, Pentech Healthcare Infusions, Inc. and subsidiaries, including the principal operating company, Pentec Health, Inc., had cash on hand of \$3.9 million. A copy of the audited financial statements of Pentech Healthcare Infusions, Inc. and subsidiaries as of December 31, 2013, is attached as Attachment, Section C, Economic Feasibility, Item 2.

Pentec's Chief Financial Officer, Art Rea, states that as of October 31, 2014, Pentec's cash on hand had increased to \$7.5 million.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- 3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.**

The estimated costs of the proposed project are set forth on the Project Costs Chart. These estimates are based on Pentec's prior experience in implementation of services in new states (particularly Kentucky, which also has a Certificate of Need requirement).

As described in the answer to Section B, Project Description, Item II.A, the proposal does not involve any construction or renovation of physical facilities, and this is reflected in the Project Costs Chart. The Legal, Administrative and Consultant Fees of \$28,500 reflect the estimated legal fees that will be incurred by Pentec in connection with the Certificate of Need filing and subsequent HHA licensure process. This estimate is derived from experience in other jurisdictions, particularly Kentucky. The estimated cost of miscellaneous office equipment of \$2,500 is based on Pentec's typical expenditure in outfitting its administrative offices in other locations, all of which are ready for occupancy when leased. The office lease expense of \$8,028 reflects the actual annual rent payable by Pentec for its leased office in Nashville. In addition to these projected costs, Pentec has budgeted an additional amount of \$100,000, described as a Contingency/Reserve Fund, to cover any unanticipated costs in connection with the Certificate of Need filing and subsequent HHA licensure process. Including the Contingency/Reserve Fund, the Estimated Project Cost is \$139,028. The CON Filing Fee of \$3,000 is based on the Estimated Project Cost.

As noted above, the project does not involve construction, so no costs per square foot are included.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- 4. Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue and expense projections for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).**

The Historical Data Chart is included on the following page, and notes to the Historical Data Chart follow on the page thereafter. The Projected Data Chart is included on page following the notes to the Historical Data Chart.

HISTORICAL DATA CHART

Give information for the last *three (3)* years for which complete data are available for the facility or agency.
The fiscal year begins in January (Month).

	Year <u>2011</u>	Year <u>2012</u>	Year <u>2013</u>
A. Utilization Data (Specify Unit of Measure)	Note 1	Note 1	Note 1
B. Revenue from Services to Patients			
1. Inpatient Services			
2. Outpatient Services	\$61,929,000	\$76,898,000	\$76,214,000
3. Emergency Services			
4. Other Operating Revenue (specify)			
Gross Operating Revenue	\$61,929,000	\$76,898,000	\$76,214,000
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments			
2. Provision for Charity Care	N/A - Not billed	N/A - Not billed	N/A - Not billed
3. Provisions for Bad Debt	\$4,003,000	\$4,943,000	\$3,047,000
Total Deductions	\$4,003,000	\$4,943,000	\$3,047,000
NET OPERATING REVENUE	\$57,926,000	\$71,955,000	\$73,167,000
D. Operating Expenses			
1. Salaries and Wages	\$18,398,000	\$23,295,000	\$26,031,000
2. Physicians' Salaries and Wages			
3. Supplies	\$12,555,000	\$18,538,000	\$18,894,600
4. Taxes	\$6,197,000	(\$5,400,000)	(\$904,000)
5. Depreciation	\$1,171,000	\$1,620,000	\$1,676,000
6. Rent	\$662,000	\$933,000	\$1,047,000
7. Interest, other than Capital	\$2,598,000	\$7,472,000	\$10,409,000
8. Management Fees			
a. Fees to Affiliates			
b. Fees to Non-Affiliates	\$250,000	\$454,000	\$600,000
9. Other Expenses (specify)	\$6,661,000	\$64,380,000	\$17,028,400
Total Operating Expenses	\$48,492,000	\$111,292,000	\$74,782,000
E. Other Revenue (Expenses) - Net (Specify)			
NET OPERATING INCOME (LOSS)	\$9,434,000	(\$39,337,000)	(\$1,615,000)
F. Capital Expenditures			
1. Retirement of Principal	N/A	N/A	N/A
2. Interest	N/A	N/A	N/A
Total Capital Expenditures	\$976,000	\$1,925,000	\$1,242,000
NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES	\$8,458,000	(\$41,262,000)	(\$2,857,000)

Notes to Historical Data Chart:

1. Utilization Date (Unit of Measure): Because revenues for Pentec Health, Inc. as a whole are derived from both its Renal Nutrition and Specialty Infusion divisions, it is not possible to specify a single unit of measure for purposes of the Historical Data Chart (in contrast to the Projected Data Chart, which reflects Specialty Infusion only and uses average patient census as the unit of measure).

Pentec's year-end intrathecal pump patient census for the three years shown is as follows:

2011: 1,303

2012: 1,783

2013: 2,177

2. Deductions from Gross Operating Revenue, Line 2, Provision for Charity Care: Pentec does not book revenue for charity care; therefore, no provision is shown in the income statement.
3. Operating Expenses, Line 4, Taxes is shown as a negative number for 2012 and 2013. This reflects the utilization of tax benefits in those years.
4. Operating Expenses, Line 9, Other Expenses includes a one-time extraordinary charge for impairment of goodwill in the amount of \$46,482,000.

PROJECTED DATA CHART

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	<u>Year 2015</u>	<u>Year 2016</u>
A. Utilization Data (Average number of patients)	20.2	52.4
B. Revenue from Services to Patients		
1. Inpatient Services		
2. Outpatient Services	304,573	853,923
3. Emergency Services		
4. Other Operating Revenue (Specify) _____		
Gross Operating Revenue	\$304,573	\$853,923
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments		
2. Provision for Charity Care	Not billed	Not billed
3. Provisions for Bad Debt	19,797	55,505
Total Deductions	19,797	55,505
NET OPERATING REVENUE	\$284,775	\$798,418
D. Operating Expenses		
1. Salaries and Wages	118,993	161,240
2. Physician's Salaries and Wages		
3. Supplies	91,234	260,130
4. Taxes	702	67,676
5. Depreciation	833	1,667
6. Rent	8,028	8,028
7. Interest, other than Capital		
8. Other Expenses (Specify) <u>One-time charges; misc.</u>	63,735	179,366
Total Operating Expenses	\$283,526	\$678,106
E. Other Revenue (Expenses) -- Net (Specify)		
NET OPERATING INCOME (LOSS)	1,249	120,312
F. Capital Expenditures		
1. Retirement of Principal		
2. Interest		
Total Capital Expenditures	\$2,500	\$2,500
NET OPERATING INCOME (LOSS)		
LESS CAPITAL EXPENDITURES	(\$1,251)	\$117,812

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- 5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.**

Please see Attachment, Section C, Need, Item 6, supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Please see Attachment, Section C, Need, Item 6, supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

Pentec's charge schedule will not change based on this proposal. Pentec is reimbursed for its services from nationwide and local insurance providers who set the charge schedule. Pentec bills according to the insurance provider's charge schedules. As such, as shown in Attachment C.I, Question 6, Pentec assumes that the charges for the proposal in Year 1 and Year 2 are equal to the actual charges incurred in 2013 from non-TN states. These figures shown are net charges, before bad debt.

A copy of Pentec's current "Home Infusion Fee Schedule" and "Miscellaneous Intrathecal Fee Schedule" is attached as Attachment, Section C, Economic Feasibility, Item 6.A.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).**

Not applicable (NA).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY****7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.**

Under its in-home patient care model, through effective management of nursing staff, Pentec is able to maintain utilization rates at or close to 100%.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- 8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.**

Pentec has determined that there are presently 1,976 Tennesseans with intrathecal pumps, and it estimates that approximately 1,020 Tennesseans are present or prospective Ig-G replacement therapy patients. Despite these numbers, Pentec has conservatively projected a Tennessee intrathecal pump patient census of 39 at year-end 2015 and 63 at year-end 2016, and it has not included Ig-G replacement therapy patients in its projections at all. Nevertheless, Pentec projects that the Tennessee HHA will have a break-even result for 2015 and a net profit of \$120,312 for 2016.

Pentec has the financial resources available to support the project regardless of whether the forecasted results are achieved. Although Pentec had a net loss in 2013 due to the impact of reduced reimbursement rates in its Renal Nutrition division, it currently projects net income of \$4.2 million in 2014. As of December 31, 2013, on a consolidated basis, Pentech Healthcare Infusions, Inc. and subsidiaries, including the principal operating company, Pentec Health, Inc., had total assets of \$207.6 million, shareholders' equity of \$53.9 million, and cash on hand of \$3.9 million. As of October 31, 2014, Pentec's cash on hand had increased to \$7.5 million.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.

1. Participation in Medicare and Medicaid

Pentec follows the NHIA Coding Standards and as such, bills insurance plans for a nursing visit, the drugs dispensed and a daily per diem rate to cover the otherwise non-billable services necessary to render this type of care. Fee-for-service Medicare and Medicaid only cover the drugs dispensed and do not cover the services necessary to administer them or manage the patient's condition. However, Pentec accepts traditional fee-for-service Medicare and Medicaid patients on a limited, compassionate care basis.

2. Service to the Medically Indigent

Pentec has developed Compassionate Care, No Insurance Coverage and Financial Assistance Policies and has implemented them in all jurisdictions in which it operates. Pentec will apply these policies to provide services to patients who are unable to pay for services. The determination of financial hardship or financial assistance to be offered will be based on the patient's ability to pay and according to Pentec's guidelines.

Pentec will attempt to collect, through good faith efforts, all outstanding balances owed by patients. However, there may be instances where the amount owed would create an undue financial hardship. In these cases, part or all of a patient's balance may be waived if financial hardship, according to the company's guidelines, has been reviewed, documented and approved. Additionally, compassionate care may be requested and approved for a limited time period, usually in 90-day increments, due to insurance reasons or other extenuating circumstances.

Formal financial evaluation is required to fairly and informatively establish the level of an individual patient's ability to pay for the portion of the charges that would be his or her responsibility. If a patient is identified (at initial set-up or during the course of therapy) as having difficulty paying the amount described as "the patient's financial responsibility" (amounts owed by the patient or the responsible party), the patient or the responsible party will be asked to complete a financial application to or provide financial information so that a determination of the patient's ability to pay can be determined in accordance with Pentec's Financial Assistance Policy.

Patients with large deductibles, out-of-pocket, coinsurance, co-pay or any other amount that would be the patient's financial responsibility will be eligible for the same financial assistance as all other patients. Because the amounts owed by patients with these types of plans can be more substantial than amounts owed by other patients, they will be analyzed using its commercial co-pay calculator. This information will be collected and used to measure profitability, but this measurement will not affect the decision to start or not start a patient on service.

At present, approximately 3% of Pentec's total patient census is comprised of compassionate care patients for which no reimbursement is received. Additionally, approximately 61% of its total patient census is currently comprised of patients for which Pentec receives compensation for some services rendered, but not all. These patients are typically Medicare and Medicaid

beneficiaries that do not have a home infusion benefit. In these cases, Pentec is usually reimbursed only for the drugs administered and assumes the patient's nursing care at a financial loss. Pentec's budgeting process assumes that 25% of the total patient census will be treated pursuant to its Compassionate Care Policy, meaning that Pentec will receive either no reimbursement, or partial reimbursement.

3. Year One Medicare and Medicaid Revenue

Pentec projects, for the first full year of HHA operation (2015), total revenue of \$304,573, of which \$43,090, or 14.1%, is from Medicare or Medicaid. As discussed above, this represents primarily revenue from drugs dispensed.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- 10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project.**

A copy of the audited consolidated financial statements of Pentec Healthcare Infusions, Inc. and subsidiaries (including its principal operating subsidiary, Pentec Health, Inc.) for the year ended December 31, 2013, is attached as Attachment, Section C, Economic Feasibility, Item 2.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:

- a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.**

Because Pentec provides specialty infusion services as a "home health agency" (or the equivalent) in all jurisdictions in which it is active, it did not consider alternatives to licensure as an HHA in Tennessee. However, as discussed in its answer to Section C.I, Question 1, Pentec believes that its in-home delivery model is more cost effective than the existing alternatives. In addition, because access will be improved and risks reduced, as discussed in its answer to Section C.I, Question 1, delivery of intrathecal pump services in the patient's place of residence is also more effective than the existing alternatives.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**ECONOMIC FEASIBILITY**

- b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

Not applicable (NA).

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

1. Managed Care Organizations

Pentec has relationships with the following managed care organizations that have plan members located in Tennessee:

Contracted:

- a. Humana, Inc.
- b. Aetna, Inc.
- c. WellPoint, Inc.
- d. Blue Cross and Blue Shield of Alabama
- e. Coventry Health and Life Insurance Company
- f. Windsor Health Plan, Inc.
- g. Independence Blue Cross
- h. Blue Cross and Blue Shield of Nebraska
- i. BlueCross BlueShield of Western New York
- j. BlueShield of Northeastern New York
- k. Blue Cross of Idaho Health Service, Inc.

Out of Network Billing Only:

- a. BlueCross BlueShield of Tennessee
- b. Cigna Corporation
- c. UnitedHealthcare
- d. Trustmark Companies
- e. SummaCare Health Plan, Inc.
- f. American Postal Workers Union Health Plan
- g. Blue Cross Blue Shield of Michigan
- h. U.S. Dept. of Health and Human Services, Pre-Existing Condition Insurance Plan
- i. Blue Cross Blue Shield of North Dakota
- j. Sterling Life Insurance Company
- k. Blue Cross & Blue Shield of Rhode Island
- l. GHI, an EmblemHealth Company
- m. Transamerica Affinity Services
- n. United Mine Workers of America
- o. Alexian Brothers Community Services
- p. CrestPoint Health
- q. MVP Health Care
- r. Providence Health Plan

2. Nurse Staffing Agencies

Pentec also has existing contracts with two nurse staffing agencies to provide registered nurses to perform Ig-G replacement therapy services only. These are:

- a. Critchfield Specialty Infusion Group, LLC
- b. Cross Country Staffing, Inc.

3. Physicians and Practices

Pentec has been in contact with a number of practitioners in Tennessee, including the following physicians and practices:

- a. Knoxville Neurology Clinic
- b. David A. Rankine, M.D. – Neurologist (Chattanooga)
- c. Chattanooga Neurology Associates
- d. Memphis Neurology
- e. Tidence L. Prince, M.D. – Immunology (Knoxville)

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

- 2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.**

Pentec is establishing relationships to physicians who practice in the field of intrathecal medicine in Tennessee. These are prospective sources of patient referrals for Pentec. Referral of patients previously treated in physicians' offices may affect those practices' utilization to a limited extent. However, Pentec believes that this would be offset by tangible benefits to the health care system as a whole. First, because the services previously provided in the physician's office (or hospital) would be provided in the patient's place of residence, access to the services would be improved. Second, the reimbursable costs associated with refills of patients' intrathecal pumps (i.e., intrathecal medications and the refill procedure) are likely to be lower than the comparable reimbursable costs if the same service were provided by a physician in an office or in a hospital. Third, the number of incidents in which an intrathecal pump patient presents at a hospital emergency department for treatment would be reduced, resulting in savings to the system. Finally, the need for emergency patient transport to an emergency department or other health care facility for treatment would be reduced, resulting in further savings to the system. Because implementation of the proposed services would have the effect of reducing the cost of services provided to intrathecal pump patients residing in Tennessee, financial competition amongst providers would be enhanced.

Although physicians practicing in the field of intrathecal medicine are capable of treating intrathecal pump patients at their practice locations, there are no licensed HHAs in Tennessee with the capability of treating these patients in their homes, on a 24/7 basis, anywhere in Tennessee. Moreover, because of the need for an HHA to provide not only skilled nursing services but also pharmacy services, the specialized training and ongoing evaluation required of nurse providers and the related investment in training, the relationships with specialists in interventional pain and spasticity management for referrals, and the required investment in technology to permit effective statewide, 24/7, in-home service, the barriers to entry by existing traditional HHAs are very high. Even amongst home health care providers that provide specialty infusion services, there are no participants with comparable nurse training programs or technological capabilities. For these reasons, Pentec expects that the proposed services would result in very little duplication of existing or proposed services.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

- 3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.**

Pentec staffs its primary care nurses at an average ratio of 40 patients to 1 nurse. Pentec has assumed in this proposal that it will be consistent and staff the Tennessee HHA at the same 40:1 ratio. In the proposal, Pentec has assumed that the HHA would initially be staffed by 1.0 FTE. A full-time primary care nurse will earn \$77,500 per year. As the Tennessee patient census increases, additional full-time primary care nurses would be hired. In addition, Pentec has a pool of registered nurses who are licensed to practice in Tennessee and available to provide part-time or backup staffing as the need arises.

Additionally, a 1/5 allocation of a Regional Nurse Manager (0.2 FTE) has been included in this proposal at a salary of \$90,000. Pentec's Regional Nurse Managers are not responsible for direct patient care, but oversee primary care nurses responsible for direct patient care. The 1/5 allocation of a Regional Nurse Manager in this proposal is consistent with the manner in which Pentec allocates its Regional Nurse Managers in all of the states in which it operates.

Pentec's full-time nursing staff is eligible for medical benefits, personal time off, and 401-k plan, all of which has been included in this proposal together with the necessary employer payroll taxes. Also included in this proposal are the professional development fees associated with nursing staff (i.e., state registered nurse licensure, etc.), as well as information technology expenses (cell phone and internet) and travel reimbursement. Both the primary care nurse salary of \$77,500 and the Nurse Manager salary of \$90,000 are above (1) the average professional and technical services industry wage in Tennessee (\$70,621) and (2) the highest average wage in the healthcare and social assistance industry wage in Tennessee (\$58,602), as reported in the 2013 Quarterly Census of Employment and Wages published by the Tennessee Department of Labor & Workforce Development.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

- 4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.**

The proposed HHA would be staffed entirely with registered nurses. As described in its answers to Section B, Project Description, Item II.A and Section C, Economic Feasibility, Item II.1, Pentec would initially staff the HHA with current employees who are already licensed to practice professional nursing in Tennessee. As the Tennessee patient census increases, Pentec would add local hires in order to maintain its target 40:1 patient to nurse ratio. All such future hires would need to satisfy the requirements of Pentec's "Primary Care Nurse" job description, including a registered nurse license from Tennessee or a compact state; and would need to complete Pentec's nurse training and certification program. Because the salary offered to primary care nurses is above average and is supplemented by an attractive benefits package, Pentec does not anticipate any difficulty in identifying and hiring additional nursing staff.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

- 5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.**

- 1. Staff Licensure**

As noted above in the answer to Section C, Contribution to the Orderly Development of Health Care, Item 4, the proposed HHA would be staffed entirely by registered nurses licensed to practice in Tennessee. Pentec currently employs full-time registered nurses who are licensed to practice in more than 30 states (including Tennessee) and the District of Columbia, so it has reviewed and understands state board of nursing licensure requirements in its national service area. In addition, Pentec employs a national "nurse regulatory manager" who tracks and ensures compliance with these requirements on an ongoing basis.

The proposed HHA would not have a medical staff.

- 2. Quality Assurance**

Pentec has adopted, and continually updates, comprehensive policies and procedures addressing all aspects of management of its home health operations and all aspects of patient care. These include a full set of policies and procedures on quality assurance entitled the "Performance Improvement Plan."

- 3. Utilization Review**

Pentec produces an annual utilization report that can be provided to the Health Services and Development Agency or the Bureau of Health Licensure and Regulation, as appropriate.

- 4. Record Keeping**

All patient medical records are housed in Pentec's secure EMR system, and they are accessible from any location (including Pentec's administrative office in Nashville) with internet service. All personnel records for the proposed HHA would be kept in Pentec's HR Department at its headquarters in Boothwyn, Pennsylvania, although copies would also be maintained at Pentec's office in Nashville. The Nashville office would also house a full set of Pentec's policies and procedures.

- 5. Staff Education**

Pentec has invested heavily in training for its primary care nurses. Although all Pentec nurse providers are licensed as registered nurses, Pentec nurses must also be specially trained to ensure that they have and maintain the skills required to administer patients' medications and monitor operation of the delivery system, which requires a rigorous program of classroom instruction, field training and ongoing proficiency evaluation by practitioners with expertise in treatment of intrathecal pump patients. Pentec's primary care nurse training program is the only such program in the United States certified by the American Nursing Credentialing Center (ANCC).

Following completion of the nurse training and certification program, Pentec nurses remain responsible for maintaining all required proficiencies on an ongoing basis. To accomplish this, Pentec's Lead Regional Nurse visits all nurses in the field at least once a year for purpose of conducting an on-site performance evaluation. Pentec nurses are required to complete an annual evaluation of all applicable standards of performance, and must demonstrate that they are competent to perform all necessary procedures. In addition, all requirements of the state Board of Nursing must be satisfied.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).

As discussed in the answer to Section C, Contribution to the Orderly Development of Health Care, Item 5, Pentec has designed and implemented a rigorous training and certification program, consisting of classroom and field training, for all of its primary care nurses. However, the proposed services will be delivered in patients' homes throughout Tennessee, rather than in a health care facility. For this reason, access by health professional schools to the services for training purposes would not be practical.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

7. a. **Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

Pentec has reviewed and understands the requirements of the Department of Health, Bureau of Health Licensure and Regulation, Division of Health Care Facilities, regarding licensure of HHAs ("Home Health Agency Procedures for Applying for Licensure of a New Facility"). In addition, it has reviewed and become familiar with the "Standards for Homecare Organizations Providing Home Health Services" as codified in Chapter 1200-08-26 of the Rules of the Tennessee Department of Health and the provisions of T.C.A. § 68-11-201 et seq.

- b. **Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.**

Licensure: Tennessee Department of Health, Bureau of Licensure and Regulation,
Division of Health Care Facilities

Accreditation: The Joint Commission

- c. **If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility.**

Pentec is presently licensed as a pharmacy in Tennessee (number 4108; expiration date February 28, 2015). A copy of the license certificate is attached as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c.

Pentec is accredited by The Joint Commission under its Home Care Accreditation Program. Pentec's current date of accreditation is June 7, 2014. Copies of Pentec's accreditation certificate and letter are attached at Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c.

- d. **For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.**

Not applicable (NA). Pentec is not an existing licensed HHA.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

Pentec received a Notice of Citation from the Indiana State Department of Health dated August 22, 2011, alleging a breach of the licensure requirements of Ind. Code § 16-27-1-15 and 410 Ind. Admin. Code § 17-10-1(a) (*In re the Matter of Pentec Health Inc.* at docket number AC-227-11). A copy of the Order is attached as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 8.

Pursuant to the Order in this matter, Pentec paid a civil penalty in the amount of \$10,000 to the Department. Pentec also submitted a plan of correction of the deficiencies found in the initial licensure survey that gave rise to the Notice of Citation and Order. Pentec's plan of correction was accepted by the Indiana State Department of Health on October 17, 2011. A copy of the Department's letter accepting the plan of correction is attached as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 8.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

- 9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.**

Not applicable (NA). There have been no such judgments for fraud or theft against any person or entity with more than a 5% ownership interest in Pentec Health, Inc.

SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED**CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE**

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Pentec produces an annual utilization report, including the number of patients treated, patient age and sex, patient location by Zip Code, type of treatment, and other relevant data, that can be provided to the Health Services and Development Agency or the Bureau of Health Licensure and Regulation, as appropriate.

PROOF OF PUBLICATION

Pentec published a "Notification of Intent to Apply for a Certificate of Need" in 15 Tennessee newspapers of general circulation between November 9 and 11, 2014 (depending on the newspapers' dates of publication), as follows:

	<u>City</u>	<u>Newspaper</u>	<u>Date</u>
1.	Bristol	Bristol Herald Courier	November 10, 2014
2.	Chattanooga	Chattanooga Times Free Press	November 10, 2014
3.	Clarksville	The Leaf-Chronicle	November 10, 2014
4.	Cookeville	Herald-Citizen	November 10, 2014
5.	Dyersburg	State Gazette	November 11, 2014 ²
6.	Greeneville	Greeneville Sun	November 10, 2014
7.	Jackson	The Jackson Sun	November 10, 2014
8.	Johnson City	Johnson City Press	November 10, 2014
9.	Kingsport	The Kingsport Times-News	November 10, 2014
10.	Knoxville	Knoxville News Sentinel	November 9, 2014
11.	Memphis	The Commercial Appeal	November 10, 2014
12.	Murfreesboro	The Daily News Journal	November 10, 2014
13.	Nashville	The Tennessean	November 10, 2014
14.	Paris	The Paris Post-Intelligencer	November 10, 2014
15.	Union City	Union City Daily Messenger	November 10, 2014

A copy of the Notification is attached. In addition, copies of the newspaper pages containing the Notification are also attached.

² Publication was scheduled for November 10, 2014, but the notice was omitted from that edition due to a newspaper error. The notice was printed in the November 11, 2014, edition instead.

PROJECT COMPLETION FORECAST CHART

Enter the Agency projected Initial Decision date, as published in T.C.A. § 68-11-1609(c): _____

Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

<u>Phase</u>	<u>DAYS REQUIRED</u>	<u>Anticipated Date (MONTH/YEAR)</u>
1. Architectural and engineering contract signed	_____	_____
2. Construction documents approved by the Tennessee Department of Health	_____	_____
3. Construction contract signed	_____	_____
4. Building permit secured	_____	_____
5. Site preparation completed	_____	_____
6. Building construction commenced	_____	_____
7. Construction 40% complete	_____	_____
8. Construction 80% complete	_____	_____
9. Construction 100% complete (approved for occupancy)	_____	_____
10. *Issuance of license	60	April 1, 2015
11. *Initiation of service	15	April 15, 2015
12. Final Architectural Certification of Payment	_____	_____
13. Final Project Report Form (HF0055)	_____	_____

For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.

Commonwealth of Pennsylvania

Department of State



CERTIFICATE OF INCORPORATION

Office of the Secretary of the Commonwealth

To All to Whom These Presents Shall Come, Greeting:

Whereas, Under the provisions of the Laws of the Commonwealth, the Secretary of the Commonwealth is authorized and required to issue a "Certificate of Incorporation" evidencing the incorporation of an entity.

Whereas, The stipulations and conditions of the Law have been fully complied with by

DELAWARE VALLEY HOME CARE CORP.

Therefore, Know Ye, That subject to the Constitution of this Commonwealth, and under the authority of the Laws thereof, I do by these presents, which I have caused to be sealed with the Great Seal of the Commonwealth, declare and certify the creation, erection and incorporation of the above in deed and in law by the name chosen hereinbefore specified.

Such corporation shall have and enjoy and shall be subject to all the powers, duties, requirements, and restrictions, specified and enjoined in and by the applicable laws of this Commonwealth.

*Given under my Hand and the Great Seal of the Commonwealth,
at the City of Harrisburg, this 28th day
of April in the year of our
Lord one thousand nine hundred and eighty-three
and of the Commonwealth the two hundred seventh*



William R. Davis

Secretary of the Commonwealth

0770579

**WRITTEN CONSENT OF THE SOLE DIRECTOR OF
PENTECH INFUSIONS, INC.**

The sole director of Pentech Infusions, Inc., a Pennsylvania corporation (the "Corporation"), in lieu of a meeting of the Board of Directors, pursuant to Section 1727(b) of the Pennsylvania Business Corporation Law of 1988, as amended, hereby consents to and adopts the following resolutions with the full force and effect as if they had been duly adopted at a meeting held pursuant to notice:

AMENDMENT TO ARTICLES OF INCORPORATION

WHEREAS, Section 1914(c) of the Pennsylvania Business Corporation Law of 1988, as amended, permits the board of directors of a corporation to amend the Corporation's Articles of Incorporation to effect a change in the Corporation's name;

WHEREAS, the sole director has determined that a change in the Corporation's name is in the best interest of the Corporation.

NOW, THEREFORE, BE IT

RESOLVED: That the name of the Corporation be changed from Pentech Infusions, Inc. to Pentec Health, Inc.

RESOLVED: That the Articles of Incorporation of the Corporation be amended such that the Articles of Amendment of the Articles of Incorporation (the "Amendment") shall read in the form of Exhibit A attached hereto; that such Amendment is hereby declared to be advisable and in the best interests of the Corporation.

RESOLVED: That the sole director of the Corporation be, and hereby is, authorized and directed to do or cause to be done any and all such other acts and things and to execute and deliver any and all such further documents as he may deem necessary or appropriate to carry into effect the full intent and purpose of the foregoing resolutions, the taking of any such actions or the execution or delivery of any such documents by the sole director to be conclusive evidence that the same were authorized by this resolution.

The undersigned has executed this Written Consent of Sole Director as of the 19th day of September, 2006.


Richard Lester, Sole Director



STATE OF TENNESSEE
Tre Hargett, Secretary of State
 Division of Business Services

William R. Snodgrass Tower
 312 Rosa L. Parks AVE, 6th FL
 Nashville, TN 37243-1102

SAUL EWING LLP
 MARONETTA F MILLER
 FL 7
 2 N 2ND ST
 HARRISBURG, PA 17101-1619

Request Type: Certified Copies

Request #: 143735

Issuance Date: 10/30/2014

Copies Requested: 1

Document Receipt

Receipt #: 1685421

Filing Fee: \$20.00

Payment-Check/MO - SAUL EWING LLP, HARRISBURG, PA

\$20.00

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that **Pentec Health, Inc.**, Control # 644762 was formed or qualified to do business in the State of Tennessee on 11/18/2010. Pentec Health, Inc. has a home jurisdiction of PENNSYLVANIA and is currently in an Active status. The attached documents are true and correct copies and were filed in this office on the date(s) indicated below.


 Tre Hargett
 Secretary of State

Processed By: Sheila Keeling

The attached document(s) was/were filed in this office on the date(s) indicated below:

<u>Reference #</u>	<u>Date Filed</u>	<u>Filing Description</u>
6794-2049	11/18/2010	Initial Filing
6842-1698	03/04/2011	Registered Agent Change (by Entity)
A0102-2539	02/01/2012	2011 Annual Report (Due 04/01/2012)

ATTACHMENT

SECTION A, APPLICANT PROFILE, ITEM 4

1. Ownership of Applicant.
2. Statement re: Financial Interests in Health Care Institutions.
3. Ownership / Organizational Chart.

1. Ownership of ApplicantA. *Pentec Health, Inc. (Applicant) is owned by the following:*

Name	Address	County	Telephone No.	Equity Interest
Pentech Holdings, Inc.	4 Creek Parkway Boothwyn, PA 19061	Delaware	800-223-4376	100.0%

B. *Pentech Holdings, Inc. is owned by the following:*

Name	Address	County	Telephone No.	Equity Interest
Pentec Healthcare Infusions, Inc.	4 Creek Parkway Boothwyn, PA 19061	Delaware	800-223-4376	100.0%

C. *Pentec Healthcare Infusions, Inc. is owned by the following (5% interest or greater):*

Name	Address	County	Telephone No.	Equity Interest
Norwest Equity Partners IX, LP	80 South 8th Street Suite 3600 Minneapolis, MN 55402	Hennepin	612-215-1600	69.06%
Norwest Mezzanine Partners III, LP	80 South 8th Street Suite 3600 Minneapolis, MN 55402	Hennepin	612-215-1600	5.06%
DW Healthcare Partners, LP	1413 Center Drive Suite 220 Park City, UT 84098	Summit	435-645-4050	10.12%
Frazier Healthcare V, L.P.	601 Union Square Suite 3200 Seattle, WA 98101	King	202-621-7200	10.12%
All other shareholders (aggregate)				5.64%
Total				100.00%

2. Financial Interests in Health Care Institutions

Neither Pentec Health, Inc. nor its owner, Pentech Holdings, Inc., has any financial or ownership interest in a Health Care Institution as defined in T.C.A. § 68-11-1602(7).

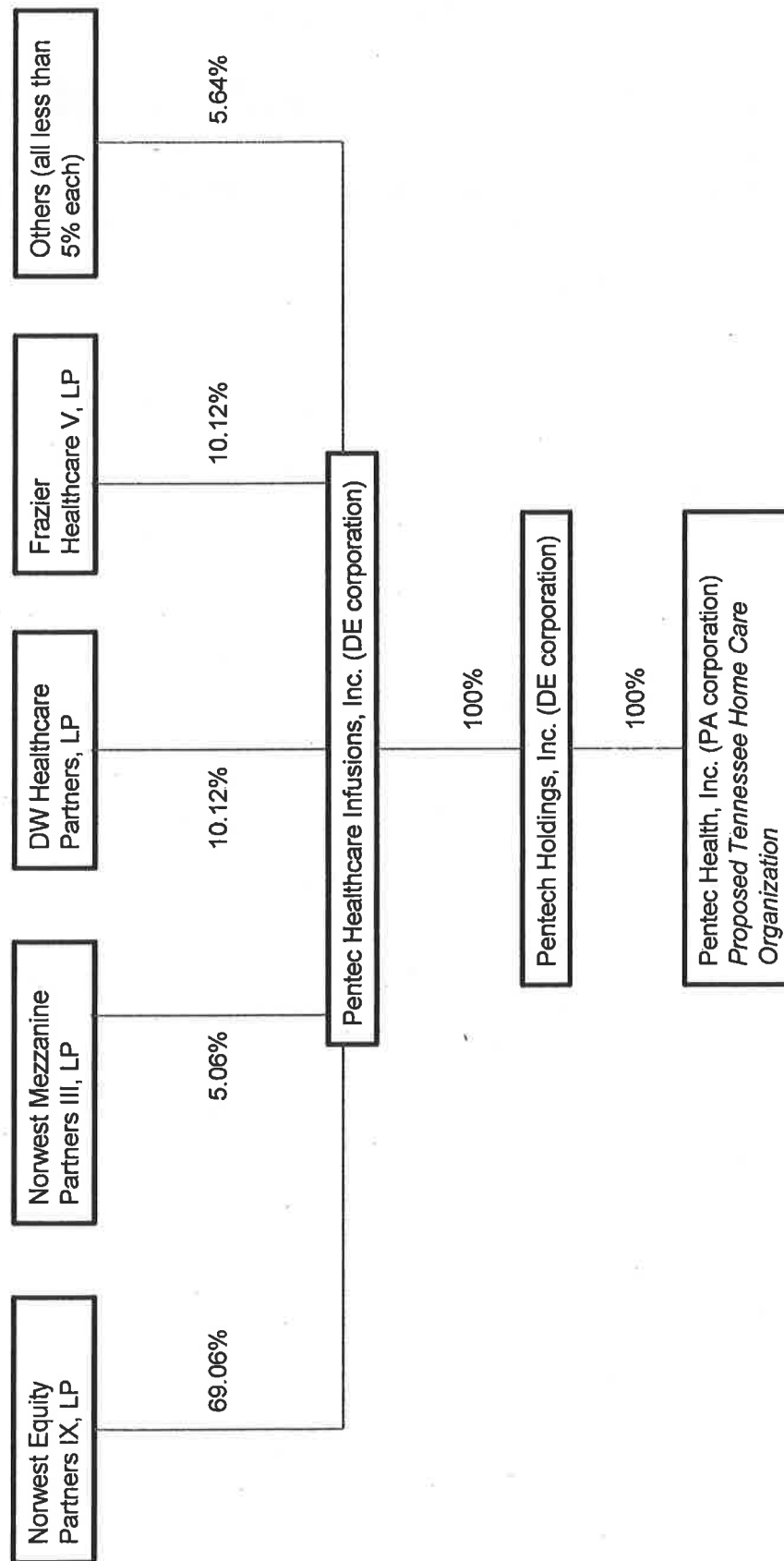
3. Ownership / Organizational Chart

An ownership / organizational chart is attached on the following page.

Pentec Health, Inc.

Organizational / Ownership Structure

As of June 30, 2014



Ownership interests in Pentech Healthcare Infusions, Inc. indicated above are fully diluted; includes vested options only

ATTACHMENT

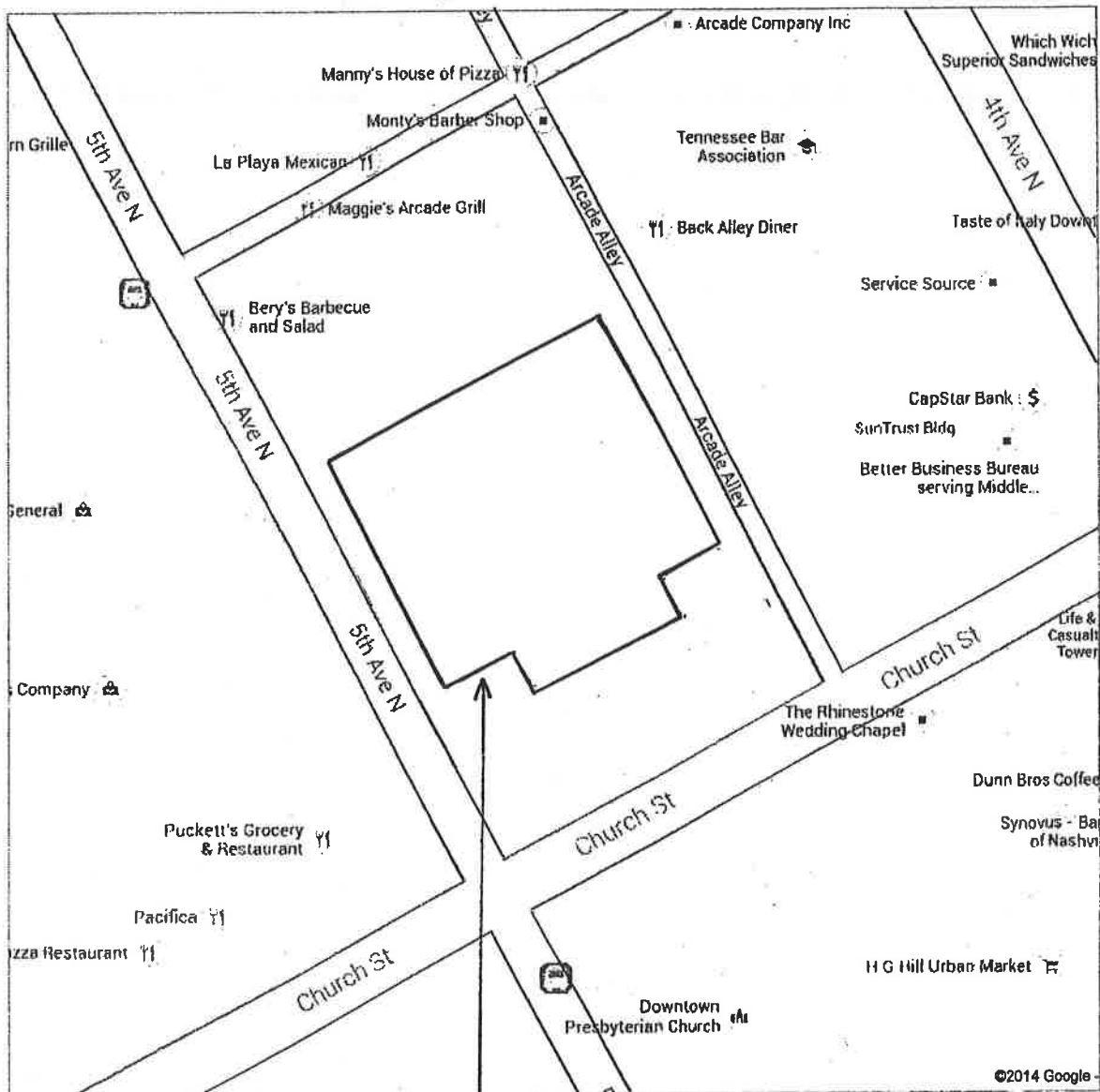
SECTION B, PROJECT DESCRIPTION, ITEM III(A)

Site plan – Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219.



Address 424 Church St
Nashville, TN 37219

NOV 25 '14 10:01



FIFTH THIRD CENTER

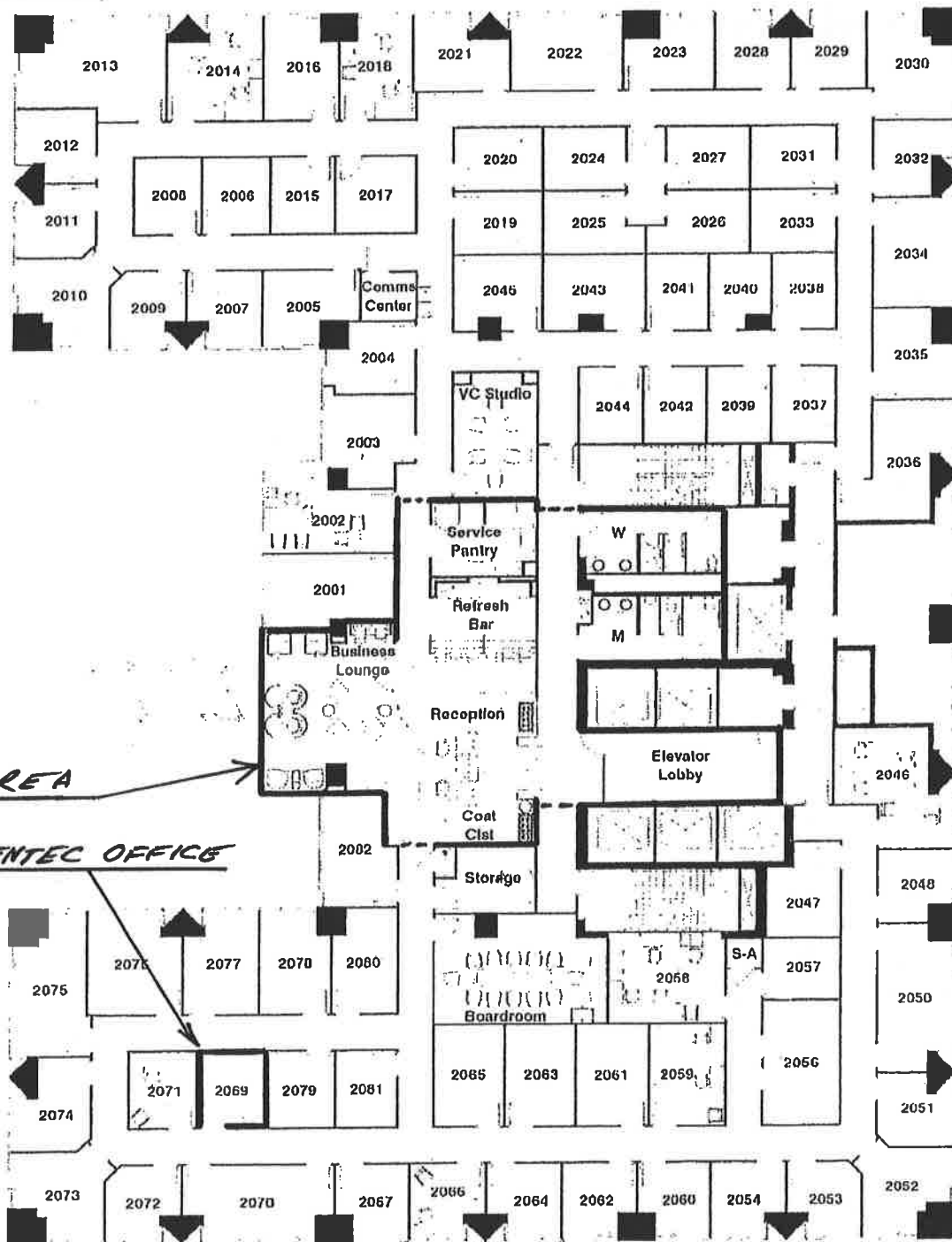
ATTACHMENT

SECTION B, PROJECT DESCRIPTION, ITEM IV

Floor plan – Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219.

Fifth Third Center

424 Church Street
Suite 2000
Nashville, TN 37219
P: 615.651.7300
F: 615.651.7301



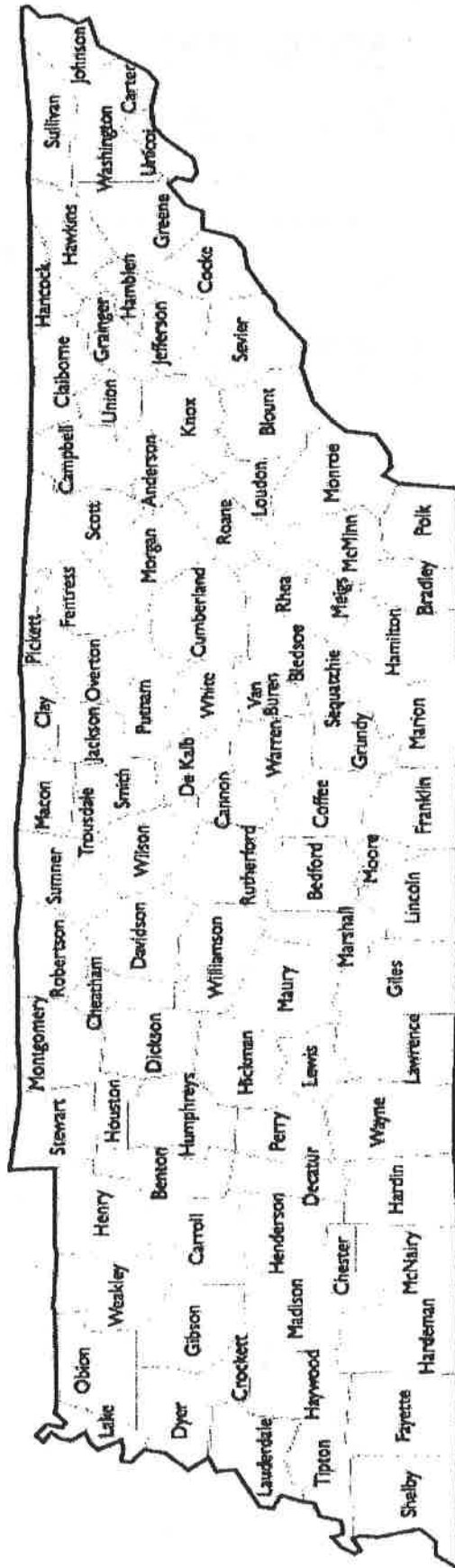
ATTACHMENT

SECTION C, NEED, ITEM 3

Map of the Proposed Service Area.



TENNESSEE COUNTY MAP



PROPOSED SERVICE AREA
ALL 95 COUNTIES IN TENNESSEE

ATTACHMENT

SECTION C, NEED, ITEM 6

1. Utilization and revenue data for Pentec Health, Inc. as a whole for the fiscal years ended December 31, 2011, 2012 and 2013; and projected utilization and revenue for the proposed Tennessee HHA for years 2015 and 2016.
2. Supporting data for the proposed Tennessee HHA for years 2015 and 2016, showing projected patient census, revenue by category, expenses and income (loss).

TOTAL COMPANY									
2011					2012				
Capacity	Actual Utilization	Revenue	Avg Charge Per Unit		Capacity	Actual Utilization	Revenue	Avg Charge Per Unit	
Per Diem	228,659	100%	13,937,317 \$	60.95	308,513	100%	18,563,320 \$	60.17	
Drugs	7,021	100%	4,459,033 \$	635.10	9,802	100%	5,279,747 \$	538.64	
Nursing	5,067	100%	451,612 \$	89.13	6,354	100%	585,109 \$	92.09	
Supplies	1,602	100%	77,537 \$	48.40	3,188	100%	112,774 \$	35.37	
Renal	14,764	100%	42,462,541 \$	2,876.09	24,683	100%	52,608,800 \$	2,131.37	
Other	N/A	N/A	540,913	N/A	N/A	N/A	-252,004	N/A	
Total Institution Revenue			\$ 61,928,953				\$ 76,897,746		

TN ONLY									
Year 1					Year 2				
Capacity	Actual Utilization	Revenue	Avg Charge Per Unit		Capacity	Actual Utilization	Revenue	Avg Charge Per Unit	
Per Diem	3,796	100%	220,940 \$	58.21	10,573	100%	615,467 \$	58.21	
Drugs	128	100%	75,441 \$	588.19	366	100%	215,101 \$	588.19	
Nursing	94	100%	6,688 \$	70.87	269	100%	19,070 \$	70.87	
Supplies	41	100%	1,503 \$	36.53	117	100%	4,285 \$	36.53	
Other	N/A	N/A	0	N/A	N/A	N/A	0	N/A	
Total			\$ 304,573				\$ 853,923		
Total TN Revenue			\$ 304,573				\$ 853,923		

Footnotes: TN Only Year 1 and Year 2 modeled after capacity usage in a state entered two years ago with an implanted pump count similar to TN. Pentec experienced reimbursement rate declines on its Renal offering in mid-2012. These rate declines did not impact the specialty infusion rates associated with the services that Pentec is proposing for TN.

\$ 33,287,995

Total Census	Census	Per Diem				Total Revenue	Census	Medicare/Medicaid				Total Revenue
		Revenue	Nursing	Drug	Supply			Revenue	Nursing	Drug	Supply	
Month 1	5	3	\$5,239	\$83	\$935	\$19	2	\$45	\$55	\$623	\$12	\$737
Month 2	5	3	\$5,239	\$83	\$935	\$19	2	\$45	\$55	\$623	\$12	\$737
Month 3	8	4	\$6,985	\$111	\$1,247	\$25	4	\$91	\$111	\$1,247	\$25	\$1,473
Month 4	8	4	\$6,985	\$111	\$1,247	\$25	4	\$91	\$111	\$1,247	\$25	\$1,473
Month 5	13	7	\$12,224	\$193	\$2,182	\$43	6	\$136	\$166	\$1,870	\$37	\$2,210
Month 6	19	10	\$17,463	\$276	\$3,117	\$62	9	\$204	\$249	\$2,806	\$56	\$3,315
Month 7	23	12	\$20,955	\$332	\$3,741	\$75	11	\$250	\$304	\$3,429	\$68	\$4,051
Month 8	26	13	\$22,702	\$359	\$4,053	\$81	13	\$295	\$359	\$4,053	\$81	\$4,788
Month 9	27	14	\$24,448	\$387	\$4,364	\$87	13	\$295	\$359	\$4,053	\$81	\$4,788
Month 10	31	16	\$27,940	\$442	\$4,988	\$99	15	\$341	\$415	\$4,676	\$93	\$5,324
Month 11	38	19	\$33,179	\$525	\$5,923	\$118	19	\$431	\$525	\$5,923	\$118	\$6,998
Month 12	39	20	\$34,925	\$553	\$6,235	\$124	19	\$431	\$525	\$5,923	\$118	\$6,998
Totals			\$218,284	\$3,455	\$38,968	\$776		\$2,656	\$3,234	\$36,474	\$727	\$43,090

Total Census	Census	Per Diem				Total Revenue	Census	Medicare/Medicaid				Total Revenue
		Revenue	Nursing	Drug	Supply			Revenue	Nursing	Drug	Supply	
Month 1	41	21	\$36,672	\$580	\$6,547	\$130	20	\$454	\$553	\$6,235	\$124	\$7,366
Month 2	45	23	\$40,164	\$636	\$7,170	\$143	22	\$499	\$608	\$6,858	\$137	\$8,102
Month 3	46	23	\$40,164	\$636	\$7,170	\$143	23	\$522	\$636	\$7,170	\$143	\$8,471
Month 4	58	29	\$50,642	\$801	\$9,040	\$180	29	\$658	\$801	\$9,040	\$180	\$10,680
Month 5	62	31	\$54,134	\$857	\$9,664	\$192	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 6	62	31	\$54,134	\$857	\$9,664	\$192	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 7	62	31	\$54,134	\$857	\$9,664	\$192	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 8	62	31	\$54,134	\$857	\$9,664	\$192	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 9	63	32	\$55,881	\$884	\$9,976	\$199	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 10	63	32	\$55,881	\$884	\$9,976	\$199	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 11	63	32	\$55,881	\$884	\$9,976	\$199	31	\$704	\$857	\$9,664	\$192	\$11,417
Month 12	63	32	\$55,881	\$884	\$9,976	\$199	31	\$704	\$857	\$9,664	\$192	\$11,417
Totals			\$607,703	\$9,618	\$108,486	\$2,161		\$7,764	\$9,452	\$106,615	\$2,124	\$125,955

Year 2	
-77,500	Allocation of RN - salary (1 FTE)
-7,440	Allocation of RN - payroll tax
-11,625	Allocation of RN - other benefits
-18,000	Allocation of RM - salary
-1,728	Allocation of RM - payroll tax
-2,700	Allocation of RM - other benefits
-91,234	COGS
-19,797	Bad Debt
-18,884	Selling expenses
-8,028	Lease expense
-45,686	G&A
1,951	EBT

ATTACHMENT

SECTION C, ECONOMIC FEASIBILITY, ITEM 2

Audited financial statements of Pentech Healthcare Infusions, Inc. and subsidiaries (including the principal operating company, Pentec Health, Inc.) as of December 31, 2013.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

~~Year Ended December 31, 2013 and for the Period~~
From June 1, 2012 (Inception) Through December 31, 2012

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

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Mayer Hoffman McCann P.C.

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INDEPENDENT AUDITORS' REPORT

To the Board of Directors of
Pentec Healthcare Infusions, Inc.

We have audited the accompanying consolidated financial statements of Pentec Healthcare Infusions, Inc. & Subsidiaries, which comprise the consolidated balance sheets as of December 31, 2013 and 2012, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, and the related notes to financial statements.

Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditors consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.



Opinion

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Pentec Healthcare Infusions, Inc. & Subsidiaries as of December 31, 2013 and 2012, and the results of their operations and their cash flows for the year ended December 31, 2013 and the period from June 1, 2012 (inception) through December 31, 2012, in accordance with accounting principles generally accepted in the United States of America.

Mayer Hoffman McCann P.C.

Plymouth Meeting, Pennsylvania
June 26, 2014

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

December 31, 2013 and 2012

	<u>ASSETS</u>	
	<u>2013</u>	<u>2012</u>
CURRENT ASSETS		
Cash	\$ 3,867,673	\$ 5,313,945
Accounts receivable, net of allowance for losses (2013 - \$1,576,499; 2012 - \$1,832,833)	12,350,668	9,906,726
Inventories	1,611,314	1,127,077
Prepaid expenses and other current assets	524,875	1,100,873
Prepaid income taxes	272,871	537,932
Deferred tax asset	2,158,435	1,419,904
TOTAL CURRENT ASSETS	<u>20,785,836</u>	<u>19,406,457</u>
PROPERTY AND EQUIPMENT, at cost, net of accumulated depreciation and amortization	<u>2,463,693</u>	<u>2,913,950</u>
OTHER ASSETS		
Goodwill	74,033,677	74,033,677
Tradenames	2,700,000	2,700,000
Amortizable intangibles, net	105,119,491	113,237,271
Deferred financing costs, net	2,343,969	2,833,155
Deposits and other long-term assets	164,434	66,792
TOTAL OTHER ASSETS	<u>184,361,571</u>	<u>192,870,895</u>
TOTAL ASSETS	<u>\$ 207,611,100</u>	<u>\$ 215,191,302</u>

	<u>LIABILITIES</u>	
	<u>2013</u>	<u>2012</u>
CURRENT LIABILITIES		
Current portion of long-term debt	\$ 4,535,923	\$ 7,089,000
Current portion of capital leases	85,460	217,836
Accounts payable	2,349,710	2,076,636
Accrued payroll and related liabilities	4,624,469	1,621,612
Credits due payors	2,255,578	989,390
Other accrued expenses	1,711,553	863,882
TOTAL CURRENT LIABILITIES	<u>15,562,693</u>	<u>12,858,356</u>
LONG-TERM LIABILITIES		
Long-term debt, less current portion above	97,214,213	103,678,430
Capital leases, less current portion above	-	87,946
Deferred tax liabilities	40,892,350	42,989,669
Deferred rent	5,960	28,386
TOTAL LONG-TERM LIABILITIES	<u>138,112,523</u>	<u>146,784,431</u>
TOTAL LIABILITIES	<u>153,675,216</u>	<u>159,642,787</u>
 <u>STOCKHOLDERS' EQUITY</u>		
CAPITAL CONTRIBUTED		
Preferred stock, \$.001 par value; 1,100,000 shares authorized, 987,855 shares issued and outstanding	988	988
Common stock, \$.001 par value; 2,750,000 shares authorized, no shares issued or outstanding	-	-
Additional paid-in capital	98,787,487	98,785,555
TOTAL CAPITAL CONTRIBUTED	<u>98,788,475</u>	<u>98,786,543</u>
ACCUMULATED DEFICIT	<u>(44,852,591)</u>	<u>(43,238,028)</u>
TOTAL STOCKHOLDERS' EQUITY	<u>53,935,884</u>	<u>55,548,515</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 207,611,100</u>	<u>\$ 215,191,302</u>

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

Year ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

	2013	2012
NET PATIENT SERVICES OPERATING REVENUE	\$ 76,213,967	\$ 43,213,481
COST OF PATIENT SERVICES	29,824,278	17,450,879
GROSS MARGIN	46,389,689	25,762,602
OPERATING EXPENSES		
Sales and marketing	8,508,141	5,542,946
General and administrative (2012 includes approximately \$1,717,000 of acquisition costs)	16,951,619	10,193,710
Depreciation and amortization	1,675,617	1,008,862
Amortization, intangibles	8,325,471	4,848,036
Provision for bad debts	3,046,089	2,809,716
Impairment of goodwill and tradenames	-	46,482,000
Stock-based compensation	1,932	1,043
TOTAL OPERATING EXPENSES	38,508,869	70,886,313
OPERATING INCOME (LOSS)	7,880,820	(45,123,711)
OTHER INCOME (EXPENSES)		
Loss on disposal of property and equipment	(14,055)	(11,462)
Interest income	24,226	13,272
Interest expense	(10,409,291)	(6,115,314)
NET OTHER INCOME (EXPENSES)	(10,399,120)	(6,113,504)
LOSS BEFORE INCOME TAX BENEFIT	(2,518,300)	(51,237,215)
INCOME TAX BENEFIT	(903,737)	(7,999,187)
NET LOSS	\$ (1,614,563)	\$ (43,238,028)

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

	Preferred Stock		Common Stock		Additional Paid-in Capital		Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Issuance of stock, June 1, 2012 (Inception)	987,855	\$ 988	-	\$ -	\$ 98,784,512	\$ -	\$ -	\$ 98,785,500
Stock-based compensation	-	-	-	-	1,043	-	-	1,043
Net loss	-	-	-	-	-	(43,238,028)	(43,238,028)	(43,238,028)
Balances, December 31, 2012	987,855	988	-	-	98,785,555	(43,238,028)	-	55,548,515
Stock-based compensation	-	-	-	-	1,932	-	-	1,932
Net loss	-	-	-	-	-	(1,614,563)	(1,614,563)	(1,614,563)
Balances, December 31, 2013	987,855	\$ 988	-	\$ -	\$ 98,787,487	\$ (44,852,591)	\$ -	\$ 53,935,884

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

	2013	2012
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (1,614,563)	\$ (43,238,028)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation and amortization	10,001,088	5,856,898
Amortization of deferred financing costs	569,186	277,795
Deferred rent	(22,426)	(52,685)
Loss on disposal of property and equipment	14,055	11,462
Stock-based compensation	1,932	1,043
Unrealized loss on interest rate cap	18,361	80,655
Deferred income taxes	(2,835,850)	(7,873,909)
Provision for bad debts	3,046,089	2,809,716
Accrued interest on subordinated long-term debt	2,868,003	2,717,430
Loss on impairment of goodwill and tradenames	-	46,482,000
Decrease (increase) in operating assets		
Accounts receivable, net	(5,490,031)	(3,229,444)
Inventories	(484,237)	261,514
Prepaid expenses and other current assets	557,637	(241,458)
Prepaid income taxes	265,061	(831,064)
Increase (decrease) in operating liabilities		
Accounts payable	273,074	(226)
Accrued payroll and related liabilities	3,002,857	(144,393)
Credits due payors	1,266,188	124,121
Other accrued expenses	847,671	(252,133)
NET CASH FLOWS FROM OPERATING ACTIVITIES	12,284,095	2,759,294
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(1,241,671)	(645,178)
Proceeds from sale of property and equipment	2,256	-
Purchase of business, net of cash	-	(202,833,547)
Cash paid for amortizable intangibles	(207,691)	(285,307)
Deposits and other long-term assets	(97,642)	(4,652)
NET CASH FLOWS FROM INVESTING ACTIVITIES	(1,544,748)	(203,768,684)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from long-term debt	-	110,000,000
Repayment of long-term debt	(11,885,297)	(1,950,000)
Repayments under capital leases	(220,322)	(130,540)
Payment of deferred financing costs	(80,000)	(253,625)
Purchase of interest rate cap	-	(128,000)
Proceeds from issuance of preferred stock	-	98,785,500
NET CASH FLOWS FROM FINANCING ACTIVITIES	(12,185,619)	206,323,335
NET INCREASE (DECREASE) IN CASH	(1,446,272)	5,313,945
CASH, BEGINNING OF PERIOD	5,313,945	-
CASH, END OF PERIOD	\$ 3,867,673	\$ 5,313,945

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS (CONTINUED)

Year Ended December 31, 2013 and for the Period From
June 1, 2012 (Inception) Through December 31, 2012

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

	<u>2013</u>	<u>2012</u>
Cash paid:		
Interest	<u>\$ 6,921,553</u>	<u>\$ 3,018,099</u>
Income taxes	<u>\$ 2,144,130</u>	<u>\$ 985,716</u>

See Notes to Financial Statements

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies

Basis of presentation - The accompanying consolidated financial statements include the accounts of Pentec Healthcare Infusions, Inc. ("Infusions") and its wholly-owned subsidiary Pentech Holdings, Inc. ("Holdings") and its wholly-owned subsidiaries, Pentec Health, Inc. ("Health"), Delaware Valley Home Care, Inc. ("DVHC"), and Pentech Home Health, Inc. ("PHH") (collectively, the "Company" or "Pentec Health"), which were acquired on June 1, 2012 (see Note 2). All significant transactions between the companies have been eliminated in consolidation.

Nature of business - Health, which started operations approximately thirty years ago, is a national, privately held, specialty infusion services company focused on providing complex pharmaceutical products and clinical services to nonhospitalized patients via cost effective methods. The Company is headquartered in Boothwyn, Pennsylvania. The Company has focused on therapies for patients suffering from chronic renal failure, chronic pain management and spasticity. The Company is reimbursed for its services by private insurance companies, Medicare under Part B and Part D, and various state Medicaid programs.

Use of estimates - The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Cash and concentration of credit risk - The Company maintains its cash at one bank which, at times, may exceed the federally insured limit.

Revenue and cost recognition - Revenue is reported at the estimated net realized amounts from third-party payors and others for pharmaceutical products and services provided to patients. These services primarily involve the distribution of specialty drugs to patients' homes or dialysis centers. Revenue is billed based upon the Company's usual and customary charges for the products and services provided, with reimbursement often indexed to Average Wholesale Price. Revenue is recognized upon confirmation of delivery of the products to the patient.

The amount of revenue recorded is based on the volume of pharmaceutical products and services provided during a given period and is based on contractual terms for the patients under healthcare plans for which there are formal agreements, historical collection experience, historical trends of refunds and payor payment adjustments, and regulatory compliance issues.

Revenue recognition uncertainties inherent in the healthcare industry are addressed in Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 954-605, "Revenue Recognition for Health Care Entities." As specified in the guidance, net revenue recognition and allowances for uncollectible billings require the use of estimates of the amounts that will ultimately be realized considering, among other items, the retroactive adjustments that may be associated with regulatory reviews, audits, billing reviews and other matters. Estimates for future audits and adjustments, which may be based on differences in the interpretation of healthcare contracts, are recorded currently as a reduction of revenue and reflected as an accrued liability.

If in a subsequent period it is determined that the original estimate of revenue was incorrect, revenue would be adjusted in that subsequent period. Infusions' adjustments have historically not been material to results of operations or financial position.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Revenue and cost recognition (continued) - Cost of patient services include all pharmaceutical costs and supplies, direct labor, subcontracting, equipment costs, as well as indirect costs related to providing medical goods to patients such as shipping and handling costs, ancillary supplies, and repair and maintenance costs of delivery vehicles.

Accounts receivable and allowance for losses - Accounts receivable are reported net of contractual adjustments and allowance for losses. The majority of the Company's accounts receivable is due from private insurance carriers and government healthcare programs such as Medicare or Medicaid.

The Company records an allowance for losses in each period based on several factors, including past accounts receivable collection history and the balance and aging composition of accounts receivable.

Inventories - Inventories, consisting of pharmaceuticals and medical supplies, are stated at the lower of cost (first-in, first-out method) or market.

Property and equipment - All property and equipment are stated at cost. Depreciation and amortization are computed on the straight-line method over the following estimated useful lives:

<u>Assets</u>	<u>Estimated Useful Lives</u>
Furniture and office equipment	7 Years
Medical equipment	3 - 10 Years
Medical equipment under capital lease	Life of Lease
Computer software and equipment	3 Years
Vehicles	5 Years
Leasehold improvements	Life of Lease

Upon retirement or disposal of property and equipment, the costs and accumulated depreciation or amortization are removed from the accounts, and any gain or loss is reflected in operations. Expenditures for maintenance and repairs are charged to operations when incurred.

Impairment of long-lived assets - In accordance with FASB ASC 360, "Accounting for the Impairment or Disposal of Long-Lived Assets," when events or circumstances warrant a review, the Company will assess recoverability of its long-lived assets from future operations using pre-tax undiscounted cash flows derived from the lowest asset groupings. Impairments are recognized in operating results to the extent that the carrying value of the long-lived asset exceeds its fair value, which is determined based on the net present value of estimated future cash flows. As of December 31, 2013 and 2012, management believes that the carrying value of these assets has not been impaired.

Goodwill and intangible assets - Goodwill represents the difference between the purchase cost of an acquired business and the fair market value of the identifiable tangible and intangible net assets acquired. In accordance with FASB ASC 350-20, goodwill and tradenames that have an indefinite life are not amortized but are reviewed for impairment annually or more frequently if certain indicators exist, by first assessing qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If the Company concludes it is more likely than not that the fair value of a reporting unit is less than its carrying amount, a quantitative fair value test is performed.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Goodwill and intangible assets (continued) - FASB ASC 350 requires a two-step process be performed to analyze whether or not goodwill has been impaired. Step one requires that the fair value of the reporting unit be compared to its carrying value. If the fair value of the reporting unit is higher than its carrying value, no impairment is indicated and there is no need to perform the second step of the process. If the fair value of the reporting unit is lower than its carrying value, step two must be evaluated. Step two requires that a hypothetical purchase price allocation analysis be done to reflect the implied fair value of goodwill. This implied fair value is then compared to the carrying value of goodwill. If the fair value is lower than the carrying value, impairment must be recorded (see Note 3).

The fair value measurements employed by the Company's impairment evaluations were generally based on a discounted cash flow approach and review of market data, which falls within Level 3 of the fair value hierarchy.

Amortizable intangible assets represent, primarily, customer relationships, proprietary technology, covenants not-to-compete, and internally developed software, which have determinate useful lives. Customer relationships, proprietary technology, covenants not-to-compete, and internally developed software are amortized over the expected life of the assets or term of the agreement, as indicated below, using the straight-line method. Amortization expense was \$8,325,471 and \$4,848,036 for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively.

Costs incurred in connection with developing a patent for a nutritional product called Proplete® have been capitalized and are amortized over the estimated life of the patent, using the straight-line method. The following is a summary of amortizable intangible assets, net of accumulated amortization, as of December 31, 2013 and 2012:

	Expected Life or Term (Years)	2013	2012
Cost			
Customer relationships	13 - 40	\$ 79,500,000	\$ 79,500,000
Covenant not-to-compete agreements	3 - 5	4,200,000	4,200,000
Proprietary technology	20	32,600,000	32,600,000
Internally developed software	3	1,500,000	1,500,000
Patents	17	492,998	285,307
Total cost		118,292,998	118,085,307
Accumulated amortization		13,173,507	4,848,036
Amortizable intangibles, net		<u>\$ 105,119,491</u>	<u>\$ 113,237,271</u>

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Goodwill and intangible assets (continued) - Annual amortization of customer relationships, covenant not-to-compete agreements, proprietary technology, internally developed software, and patents for each of the next five years is as follows:

Years Ending December 31.

2014	\$	8,332,205
2015	\$	8,040,538
2016	\$	6,959,982
2017	\$	6,725,538
2018	\$	6,725,538
Thereafter	\$	68,335,690

Deferred financing costs - Costs incurred to secure the Company's long-term debt are being amortized on the straight-line method over the term of the related debt, six years. Accumulated amortization as of December 31, 2013 and 2012 was \$846,981 and \$277,795, respectively. Amortization expense for the year ended December 31, 2013 and for the period from June 1, 2012 (Inception) through December 31, 2012, was \$569,186 and \$277,795 respectively, and is included in interest expense. Annual amortization of deferred financing costs for each of the next five years is as follows:

Years Ending December 31.

2014	\$	556,496
2015	\$	523,163
2016	\$	523,163
2017	\$	523,163
2018	\$	217,984

Stock-based compensation plan - The Company is required to recognize compensation expense for options granted over the vesting period of the option commencing with the date the option is granted. The Company accounts for stock option awards using the fair market value method.

Income taxes - The Company is required to recognize deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized in its consolidated financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the differences between the consolidated financial statements carrying amounts and tax bases of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Accounting for derivative instruments and hedging activities - The Company accounts for its derivative instruments and hedging activities under FASB ASC 815. FASB ASC 815 requires the Company to measure every derivative instrument (including certain derivative instruments embedded in other contracts) at fair value and record them in the consolidated balance sheets as either an asset or liability.

As part of the credit agreement the Company entered into on June 1, 2012, the Company was required to obtain an interest rate cap. The changes in fair value of the interest rate cap are recorded in earnings.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Accounting for uncertain tax positions - The Company accounts for the effect of any uncertain tax positions based on a "more likely than not" threshold applied to the recognition of the tax positions being sustained based on the technical merits of the position under scrutiny by the applicable taxing authority. If a tax position or positions are deemed to result in uncertainties of those positions, the unrecognized tax benefit is estimated based on a "cumulative probability assessment" that aggregates the estimated tax liability for all uncertain tax positions.

The Company files a consolidated U.S. federal income tax return as well as various state income tax returns. The Company does not believe there will be any material changes in its unrecognized tax positions over the next twelve months. The Company has not incurred any interest or penalties. In the event that the Company is assessed interest or penalties at some point in the future, they will be classified in the consolidated financial statements as general and administrative expenses.

Fair value measurements - The Company follows FASB ASC 820 which defines fair value and establishes a hierarchy for reporting the reliability of input measurements used to assess fair value for all assets and liabilities. Fair value is defined as the selling price that would be received for an asset, or paid to transfer a liability, in the principal or most advantageous market on the measurement date. The hierarchy established prioritizes fair value measurements based on the types of inputs used in the valuation technique. The inputs are categorized into the following levels:

- Level 1 - Observable inputs such as quoted prices in active markets for identical assets or liabilities;
- Level 2 - Directly or indirectly observable inputs for quoted and other than quoted prices for identical or similar assets and liabilities in active or nonactive markets; and
- Level 3 - Unobservable inputs not corroborated by market data, therefore requiring the entity to use the best information available in the circumstances, including the entity's own data assumptions.

The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability. FASB ASC 820 was applied to the Company's outstanding derivatives effective December 31, 2013 and 2012.

The following table sets forth the Company's financial asset that was accounted for at fair value on a recurring basis:

Fair Value Measurements as of December 31, 2013				
	Level 1	Level 2	Level 3	Balance
Assets				
Interest rate cap	\$ -	\$ 7,650	\$ -	\$ 7,650

Fair Value Measurements as of December 31, 2012				
	Level 1	Level 2	Level 3	Balance
Assets				
Interest rate cap	\$ -	\$ 26,011	\$ -	\$ 26,011

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(1) Summary of significant accounting policies (continued)

Fair value measurements (continued) - The interest rate cap agreement, which is included in prepaid expenses and other current assets on the accompanying consolidated balance sheets, is recorded at fair value based upon valuation models utilizing the income approach and commonly accepted valuation techniques that use inputs from closing prices for similar assets and liabilities in active markets as well as other relevant observable market inputs at quoted intervals such as current interest rates, forward yield curves, implied volatility, and credit default swap pricing. The Company does not believe the ultimate amount that could be realized upon settlement of the interest rate cap agreement would be materially different from the fair values currently reported.

The inputs or methodology used to measure fair value of such a financial asset may not be necessarily indicative of all of the risks associated with such financial assets.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, net, accounts payable, accrued expenses, credits due payors, and capital leases approximate the respective fair values due to the short maturities for those instruments. The recorded amount of the debt approximates the fair value due to the variability of the associated interest rate.

(2) Business acquisition

On June 1, 2012, Infusions acquired all of the outstanding preferred and common stock of Holdings. The total purchase price was approximately \$200,000,000. In connection with the acquisition, \$11,750,000 was placed in escrow as security against certain financial and legal contingencies, and was settled in September 2013.

The acquisition was accounted for using the purchase method of accounting in accordance with ASC 805, "Business Combinations," and, accordingly, the Company's consolidated results of operations include the results of the Company from the acquisition date.

In connection with the acquisition, the Company raised approximately \$99,000,000 with the sale of preferred stock. The Company also obtained approximately \$78,000,000 of long-term debt, a revolving credit obligation of approximately \$7,000,000, and \$32,000,000 of subordinated debt. No amount was borrowed on the available revolving credit obligation at the time of the acquisition. Also, in connection with the acquisition, the Company incurred approximately \$1,717,000 of acquisition costs, which are included in general and administrative expenses on the consolidated statements of operations.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(2) Business acquisition (continued)

A summary of the total consideration and assets acquired in the acquisition as of June 1, 2012, is as follows:

Consideration	
Equity raised	\$ 98,786,000
Debt incurred	110,000,000
Liabilities assumed (including \$50,665,000 of deferred tax liabilities)	57,299,000
Total consideration	<u>266,085,000</u>
Assets acquired	
Cash	5,952,000
Accounts receivable	9,487,000
Inventories	1,389,000
Prepaid expenses and other current assets	812,000
Deferred tax asset	1,221,000
Property and equipment	3,289,000
Deferred financing costs	2,857,000
Deposits and other long-term assets	62,000
Customer relationships	79,500,000
Noncompete agreements	4,200,000
Proprietary technology	32,600,000
Internally developed software	1,500,000
Tradenames	19,300,000
Total assets	<u>162,169,000</u>
Goodwill	<u>\$ 103,916,000</u>

The goodwill arising from the acquisition consists largely of expected future earnings and cash flows from the continued growth of the Company.

(3) Goodwill and Tradenames

As discussed in Note 2, Infusions acquired goodwill and tradenames in connection with the acquisition of Holdings. Goodwill represents the excess of purchase price over the fair value of net assets acquired. Under FASB ASC 350, goodwill and intangible assets that have indefinite lives are reviewed for impairment annually or more frequently if certain indicators arise. Infusions has evaluated the carrying value of goodwill and its identifiable intangible assets that have indefinite lives as of December 31, 2013 and 2012, utilizing discounted cash flows, among several different valuation approaches. After evaluating the discounted cash flows, management concluded that the carrying value of goodwill and tradenames did not exceed their fair values at December 31, 2013; thus, no impairment occurred during the year ended December 31, 2013. However, for the period from June 1, 2012 (Inception) through December 31, 2012, after evaluating the discounted cash flows, management concluded that the carrying value of goodwill and tradenames exceeded their fair values at December 31, 2012, and, therefore, were impaired. In accordance with FASB ASC 350, these intangible assets will continue to be assessed on an annual basis, and impairment, if any, will be recorded as a charge against income from operations.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(3) Goodwill and Tradenames (continued)

In July 2012, the Company recognized that the Medicare Part D reimbursement rates were being significantly decreased for the two key ingredients in their Proplete® formula used in servicing the Company's renal patients. This sudden change in the reimbursement rate resulted in an immediate Medicare Part D reimbursement rate decrease of more than 75%. Due to this substantial decrease in the reimbursement rates, the Company has revised and modified its projected future revenue and cash flow forecasts. The effect these changes had on the period from June 1, 2012 (inception) through December 31, 2012's actual gross margin as compared to budgeted gross margin for the same period was significant with actual gross margin declining from a budgeted 74.2% to an actual 63.1% for the renal division. The Company believes that this reduction in reimbursement rates and related profitability trends will continue for the foreseeable future and thus will have a significant negative effect on the estimated future operating results and cash flows. The Company reduced its work force during November 2012, in response to these uncertainties.

The first step of the FASB ASC 350 impairment analysis consists of a comparison of the fair value of the goodwill and tradenames with its carrying amount. The fair value was determined based on an average of four different valuation approaches. Based on this analysis, the Company determined the carrying amount of the goodwill and the tradenames was in excess of their respective fair values. As such, the Company was required to perform the second step analysis in order to determine the amount of the goodwill and tradenames impairment. The second step analysis consisted of comparing the implied fair value of the goodwill and tradenames with the carrying amount of the goodwill and tradenames, with an impairment charge resulting from any excess of the carrying value of the goodwill and tradenames over the respective implied fair values. Based on the second step analysis, the Company concluded that the goodwill and tradenames were impaired by approximately \$29,882,000 and \$16,600,000, respectively, as of December 31, 2012. As a result, the Company recorded a noncash goodwill impairment charge which is included in operating expenses totaling \$46,482,000 for the period from June 1, 2012 (inception) through December 31, 2012.

The determination as to whether a write-down of goodwill and other indefinite-lived intangibles is necessary involves significant judgment based on short-term and long-term projections of the Company. The assumptions supporting the estimated future cash flows, including profit margins, long-term forecasts, discount rates and terminal growth rates, reflect the Company's best estimates.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(4) Property and equipment

The following is a summary of property and equipment, net of accumulated depreciation and amortization, as of December 31, 2013 and 2012:

	2013	2012
Cost		
Furniture and office equipment	\$ 282,714	\$ 162,968
Medical equipment	177,624	85,632
Medical equipment under capital lease	356,547	394,697
Computer software and equipment	2,530,378	1,919,514
Vehicles	2,812	6,812
Leasehold improvements	1,766,892	1,349,779
Total cost	5,116,967	3,919,402
Accumulated depreciation and amortization	2,653,274	1,005,452
Property and equipment, net	<u>\$ 2,463,693</u>	<u>\$ 2,913,950</u>

Depreciation and amortization expenses for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, was \$1,675,617 and \$1,008,862, respectively. During the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, the Company disposed of depreciated property and equipment with an original cost of approximately \$44,000 and \$15,000, respectively, and net book value of approximately \$16,000 and \$11,000, respectively.

(5) Major customers, vendors and concentration of credit risks

The Company provides nutritional and pharmaceutical products to patients nationally. The Company grants credit to these customers by accepting assignment on medical claims filed seeking reimbursement. Consequently, the Company's ability to collect amounts due from its payor sources may be affected by the creditworthiness of these payors and the possible subsequent review of claims for medical appropriateness and insurance coverage. Management believes these risks are mitigated as the Company secures authorizations prior to beginning service.

Patients are referred to the Company by dialysis centers owned by third parties. As of December 31, 2013 and 2012, there was one referral source that generated 34% and 31.5% of patient census, respectively.

One payor accounted for approximately 23% and 16% of revenues for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively. Accounts receivable from this payor as of December 31, 2013 and 2012 was approximately \$7,005,000 and \$2,597,000, respectively. Also approximately 26% and 33% of revenues for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively, were paid by approximately 50 unique third-party payors under the Medicare Part D program. Accounts receivable from payors under the Medicare Part D program was approximately \$1,474,000 and \$1,011,000 as of December 31, 2013 and 2012, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(5) Major customers, vendors and concentration of credit risks (continued)

The Company has contracts with various vendors for the purchase of pharmaceuticals and medical supplies. One vendor accounted for approximately 50% and 59% of purchases for these products for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively. The Company believes that it would be able to either obtain its inventory from other companies or take alternative steps to obtain similar products in certain cases. The Company owed the vendor approximately \$680,000 and \$749,000 as of December 31, 2013 and 2012, respectively.

(6) Revolving credit facility

In June 2012, the Company obtained a new revolving credit facility of \$7,000,000, of which \$0 was outstanding as of December 31, 2013 and 2012, respectively. Borrowing is limited to a borrowing base calculation of the difference of EBITDA multiplied by the maximum Senior Debt to EBITDA ratio allowed under the credit agreement (ranging from 2.00 to 3.50) less outstanding senior debt.

The revolving credit facility matures on May 31, 2018. The interest rate is either the prime rate plus an applicable margin ranging from 4.00% to 4.50% or LIBOR plus an applicable margin ranging from 5.00% to 5.50% (with a floor of 1.25% for LIBOR) at the Company's option and is subject to certain debt covenants. As of December 31, 2013 and 2012, the interest rate for the facility was based on LIBOR at a rate of 6.5%. The facility is cross-collateralized with the credit agreement (see Note 7).

On December 31, 2012, the Company entered into a First Amendment ("First Amendment") to its revolving credit facility. The First Amendment modified the available credit facility to be the lesser of the revolving loan commitment or \$2,500,000, provided that the Company deliver the consolidated financial statements and a covenant compliance certificate demonstrating that the Senior Debt to EBITDA ratio as of the last day of a computation period is less than 3.50 to 1.00. Borrowing is limited to a borrowing base calculation of the difference of EBITDA multiplied by the maximum Senior Debt to EBITDA ratio allowed under the credit agreement (ranging from 3.50 to 7.00) less outstanding senior debt. The interest rate is either the prime rate plus an applicable margin ranging from 4.0% to 5.0% or LIBOR plus an applicable margin ranging from 5.0% to 6.5% (with a floor of 1.25% of LIBOR) at the Company's option and is subject to certain debt covenants.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(7) Long-term debt

As of December 31, 2013 and 2012, the Company's long-term debt obligations consisted of the following:

	<u>2013</u>	<u>2012</u>
Credit agreement payable to several banks with quarterly principal payments ranging from \$907,185 to \$1,814,369 with a final payment of approximately \$38,764,000, plus monthly interest (6.5% as of December 31, 2013). The quarterly payments are due from September 30, 2012 through May 31, 2018.	64,164,703	\$ 76,050,000
Subordinate credit agreement payable with principal and all accrued interest due May 31, 2018. Due to the amendment noted below, all interest (14% as of December 31, 2013) is to be considered payment-in-kind, including \$5,585,433 and \$2,717,430 accrued as of December 31, 2013 and 2012, respectively.	37,585,433	34,717,430
Long-term debt	101,750,136	110,767,430
Less current portion	4,535,923	7,089,000
Long-term debt, net of current portion	<u>\$ 97,214,213</u>	<u>\$ 103,678,430</u>

Scheduled annual maturities of long-term debt as of December 31, 2013 are as follows:

Years Ending December 31,

2014	\$ 4,535,923
2015	5,443,107
2016	6,350,292
2017	7,257,476
2018	78,163,338
	<u>\$ 101,750,136</u>

On June 1, 2012, the Company entered into a senior credit facility for a term loan totaling approximately \$78,000,000. The proceeds of the loan were used to purchase Holdings from its stockholders (see Note 2). The term of the loan is amortized over twenty-four quarterly payments of principal ranging from approximately \$907,185 to \$1,814,369 from December 2013 through May 2018, with a balloon payment of approximately \$38,764,000 due in May 2018. Interest is based on whether or not the term loan is considered to be a "Base Rate Loan" or a "LIBOR" loan. If the term loan is considered to be a "Base Rate Loan," the Company pays interest equal to the bank's prime rate, plus an applicable margin. If the Company opts to engage in a LIBOR contract, the term loan is considered to be a "LIBOR" loan and the Company pays interest equal to the sum of the LIBOR applicable to each interest period and the applicable margin. Interest is paid based on the loan contract term. The term loan includes various financial and nonfinancial covenants, including a minimum EBITDA, leverage ratios, and a minimum fixed coverage ratio.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(7) Long-term debt (continued)

On December 31, 2012, the Company entered into a First Amendment to its term loan. The First Amendment modified certain loan covenants, including but not limited to: modified the interest rate pricing grid (applicable margin); required quarterly mandatory prepayments of any cash on hand in excess of \$5 million beginning March 31, 2013, until senior leverage is less than 4.00 times; modified the excess cash flow percentage; updated the reporting requirements; modified the definitions of EBITDA and fixed charges and limited the payments of the subordinated debt, related-party management fees, and senior management bonuses.

In connection with the First Amendment, the Company is required to pay the higher result of either the excess cash flow calculation as defined in the agreement, as of December 31, 2012, or the required excess cash sweep prepayment noted above, as of March 31, 2013. The prepayment, which was made in April 2013, was applied in the inverse order of maturities due on the term loan. This required prepayment of approximately \$3,189,000 was included in the current portion of the long-term debt included in the consolidated balance sheet as of December 31, 2012. The scheduled annual maturities provided above have been modified for this required prepayment.

Prior to the First Amendment, the interest rate for the term loan was either the prime rate, plus an applicable margin ranging from 4.0% to 4.5%, or LIBOR (with a floor of 1.25%), plus an applicable margin ranging from 5.0% to 5.5%, at the Company's option. As of December 31, 2013, the Company had chosen the LIBOR option (6.5%). The loan facility also required an annual prepayment based on excess cash flows and an interest rate cap. The annual prepayment based on excess cash flows is applied ratably on the remaining outstanding debt. Collateral for the loan consists substantially of all of the assets of the Company.

In May 2013, the Company made a voluntary prepayment of \$5,000,000. The voluntary prepayment is applied to the outstanding principal, results in lower quarterly principal payments and interest payments, and was credited towards the 2013 excess cash flow calculation.

The Company entered into a 48-month interest rate cap in July 2012, for approximately \$128,000. The Company is exposed to interest rate risk primarily through its borrowing activities. The Company's long-term borrowing is a variable rate instrument.

The Company designated the interest rate cap as a fair value hedge. As of December 31, 2013 and 2012, there has been a reduction in the fair value of the hedge to approximately \$8,000 and \$26,000, respectively. The change in the interest rate cap was recorded in operations and is included in interest expense in the accompanying consolidated statements of operations.

On June 1, 2012, the Company entered into a credit facility for a subordinate term loan totaling approximately \$32,000,000. The proceeds of the loan were used to purchase Holdings from its stockholders (see Note 2). The term of the loan requires a one-time principal payment in June 2018, along with all unpaid interest. Interest is due quarterly. In September 2012, the Company obtained a waiver from the first interest payment, which continued through the quarter ended March 31, 2013 - these payments were deemed payment-in-kind interest and added to the outstanding loan balance. The subordinate term loan includes various financial and nonfinancial covenants, including a minimum EBITDA, fixed charge ratio, and leverage ratios. For the year ended December 31, 2013 and for the period of June 1, 2012 (inception) through December 31, 2012, the interest rate for the subordinate term loan was 14% per year (2% of which is considered payment-in-kind, which is added to the principal on a quarterly basis).

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(7) Long-term debt (continued)

On December 31, 2012, the Company entered into a First Amendment to its subordinate term loan. The First Amendment modified certain loan covenants, including but not limited to: deferred all interest payments until certain senior leverage requirements are met; updated the reporting requirements; modified the definitions of EBITDA and fixed charges, and deferred the payment of related-party management fees to the extent not permitted to be paid per the terms of the senior credit facility.

For the reporting period ending March 31, 2013, the Company had met the required senior leverage requirements to resume making interest payments. On June 30, 2013, the Company resumed making interest payments.

In December 2013 and March 2014, the Company obtained waivers from paying the respective quarterly interest payments - these payments were deemed payment-in-kind interest and added to the outstanding loan balance.

(8) Commitments and contingencies

Operating leases - The Company conducts its operations at its facility located in Boothwyn, Pennsylvania.

The Company has a lease for corporate office space. The corporate office is leased under a seven-year noncancelable operating lease expiring in 2015, which provides for monthly rental payments of \$45,943, with an option to renew the lease for an additional five years.

As part of the lease, the Company was provided a build-out allowance of \$565,000 which reduces rent expense over the term of the lease. Leasehold improvements incurred in connection with the lease are amortized over the life of the lease.

The Company has two addendums to the above lease for additional space. The addendums are leases for approximately four years, expiring in 2015, which provide for monthly rental payments ranging from \$8,043 to \$8,862, for both addendums.

During 2013, the Company entered into new operating leases for additional office space and medical equipment. The office lease, with monthly rental payments of \$4,170, expires in May 2016, and may be extended for two additional three-year terms. The medical equipment leases, with monthly payments of \$2,250, expire in April 2018.

Total rent expense for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, was approximately \$1,573,000 and \$886,000, respectively. Included in rent expense is approximately \$568,000 and \$533,000, respectively, related to medical equipment and \$92,000 and \$41,000, respectively, related to office space, which is leased on a month-to-month basis for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012. The medical equipment leases contain an option to enter into a capital lease with that vendor.

Capital leases - The Company has two capital leases for certain medical equipment with a value of \$316,194 and \$93,375, respectively, as of June 1, 2012. The leases are payable in monthly installments of \$32,640 and \$5,880, respectively, including interest at 13%, through March 31, 2014 and November 30, 2014, respectively. As of December 31, 2013 and December 31, 2012, the accumulated depreciation related to the assets purchased under these two capital leases is \$289,337 and \$117,821, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(8) Commitments and contingencies (continued)

Future annual minimum lease commitments under all capital and noncancelable operating leases as of December 31, 2013, are as follows:

<u>Years Ending December 31,</u>	<u>Capital Leases</u>	<u>Operating Leases</u>
2014	\$ 159,280	\$ 842,214
2015	-	784,619
2016	-	47,849
2017	-	27,000
2018	-	9,000
Total minimum lease payments	159,280	\$ 1,710,682
Less amount representing interest and service fees	73,820	
Present value of net minimum lease payments	85,460	
Less current portion of the capital lease obligation	85,460	
	<u>\$ -</u>	

Subsequent to December 31, 2013, the Company entered into two capital leases for certain medical equipment with a value of approximately \$309,000 and \$2,022,000, respectively. The terms of each lease is four years and the monthly payments are \$7,321, including interest at 6.5%, and \$94,200, including interest at 13%, respectively.

Legal - The Company is subject to claims which arise in the ordinary course of business. Management believes that the ultimate outcome of these claims will not have a material effect on the Company's financial position or results of operations.

(9) Equity transactions

Preferred stock - In June 2012, the Company authorized 1,100,000 shares with a par value of \$0.001. The Company has designated that 1,000,000 shares are convertible to common stock and issued 987,855 shares of Series A Convertible preferred stock.

Conversion - Each share of the issued Series A preferred stock is convertible, at the option of the holder, at any time, into a number of fully paid and nonassessable shares of common stock that is equal to the Series A Preferred Stock Liquidation Value as of the conversion date divided by the Series A Conversion Price. The Series A Conversion Price is \$100.00.

The Company shall have the right to cause some or all of Series A preferred stock to be automatically converted at any time after the date of issuance of such shares at the conversion rate stated above. In case of any conversion of part of the shares of Series A preferred stock at the time outstanding, the shares to be so converted shall be selected pro rata from among the holders thereof.

Dividends - The holders of the Series A preferred stock are entitled to receive cumulative cash dividends at the annual rate of ten percent (10%) of the Series A original issue price (\$100.00) for each share of Series A preferred stock outstanding. Such dividends shall be cumulative in nature and paid in full before any dividend or other distribution shall be paid or declared. Such dividends began accruing as of the original issue date. As of December 31, 2013 and 2012, cumulative undeclared dividends were approximately \$15,640,000 and \$5,762,000, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(9) Equity transactions (continued)

Liquidation preference - In the event of any liquidation, dissolution or winding up of the Company, the holders of the Series A preferred stock are entitled to receive prior to, and in preference to, any distribution to the common stockholders, an amount equal to the greater of (A) an amount equal to (x) the number of shares of Series A preferred stock held by such holder multiplied by (y) the then applicable Series A preferred Stock Liquidation Value or (B) the amount that would be payable in such Liquidation with respect to shares of common stock issuable to such holder upon the conversion of shares of Series A preferred stock held by such holder had such shares of Series A preferred stock been converted into common stock immediately prior to such Liquidation. In the event that upon liquidation or dissolution, the assets are insufficient to permit the payment to preferred stockholders of the full preferential amounts, then all assets legally available for distribution are to be distributed ratably among the holders of the shares of Series A preferred stock.

Voting rights - Each Series A preferred stockholder is entitled to the number of votes equal to the number of shares of common stock into which such holder's shares are convertible.

Common stock - As of December 31, 2013 and 2012, the Company has authorized the issuance of 2,750,000 shares of common stock, with a par value of \$0.001 as follows:

Issued and outstanding common stock	-
Reserved under stock option plan	151,083
Reserved for Series A preferred stockholders	987,855
Unreserved	<u>1,611,062</u>
Total authorized	<u><u>2,750,000</u></u>

The voting, dividend and liquidation rights of the holders of the common stock are subject to and qualified by the rights of the holders of the Series A preferred stock and by the Board of Directors, upon any issuance of the preferred stock of any series. The holders of common stock are entitled to one vote for each share held at all meetings of stockholders. All shares of common stock will be identical and will entitle holders to the same rights and privileges.

(10) Stock option plan

In June 2012, the Board of Directors adopted the Pentec Healthcare Infusions, Inc. 2012 Stock Option Plan, which allows for the issuance of options, from time to time. The common shares available under the Plan is 151,083 common shares.

During the period from June 1, 2012 (inception) through December 31, 2012, the Company granted certain key individuals options to purchase 55,203 shares of the Company's stock at \$100.00, which was intended to approximate the estimated fair value of the stock on the grant date (Pool A). The estimated value for these options is \$0.15 per option based on the valuation of the options. The options vest over five years from the date of grant, with 20% vesting on the first anniversary of the grant date and then 20% of the remaining options vesting each year, thereafter. The options are exercisable from the time they vest through a period of ten years from the date of grant. Total compensation expense related to these options issued during 2012, in accordance with FASB ASC 718, is approximately \$8,300 which will be recognized over the five-year vesting period. The amount of expense recognized during the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, is approximately \$1,700 and \$1,000, respectively.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(10) Stock option plan (continued)

During the period from June 1, 2012 (inception) through December 31, 2012, the Company granted certain key individuals, options to purchase 55,203 shares of Company stock at \$100, which was intended to approximate the estimated fair value of the stock on the grant date (Pool B). The options vest when there is a change of control and an internal rate of return of at least 15% and a cash-on-cash return of at least 2.25 times, as defined in the agreement. The estimated value for these options is \$0.01 per option based on the valuation of the options. Total compensation related to these options issued in 2012, in accordance with FASB ASC 718, is approximately less than \$1,000 which will be recognized over the requisite service period. Total compensation expense related to these options recognized during the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, is approximately \$300 and \$100, respectively.

During the period from June 1, 2012 (inception) through December 31, 2012, the Company granted certain key individuals options to purchase 34,865 shares of the Company's stock at \$100, which was intended to approximate the estimated fair value of the stock on the grant date. The options vest when there is a change of control and an internal rate of return of at least 20% and a cash-on-cash return of at least 3.5 times (Pool C) as defined in the agreement. The estimated value for these options is \$0.00001 per option based on the valuation of the options. Total compensation related to these options issued in 2012, in accordance with FASB ASC 718, is approximately less than \$1 which will be recognized over the requisite service period. Total compensation expense recognized during both the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, is less than \$1.

Subsequent to December 31, 2013, the vesting requirements of Pools B and C were modified. The vesting condition related to the internal rate of return requirement was eliminated from both pools and the cash-on-cash requirement was reduced to at least 1.5 times for Pool B and at least 2.5 times for Pool C. There was no modification to the change of control vesting requirement.

During the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, the Company recognized approximately \$2,000 and \$1,000 as compensation costs relate to all options issued, respectively. The remaining unrecognized compensation cost of approximately \$5,700 will be recognized over the remaining vesting period of up to approximately three years.

For options granted during the period from June 1, 2012 (inception) through December 31, 2012, the Company calculated the fair value of the options using the Black-Scholes option valuation model that uses the assumptions noted in the following table. The Company calculated its expected volatility using the average of several comparable public companies. The Company elected to use the average of comparable companies because it did not have a trading history for its stock. The Company chose comparable companies that are closely related to its industry and averaged them to give a better representation of the expected volatility. The Company uses historical data to estimate option exercise and employee termination within the valuation model. The expected term of options granted is derived from the output of the option valuation model and represents the period of time that options granted are expected to be outstanding. The risk-free interest rate for periods within the contractual life of the option is estimated based on the U.S. Treasury yield curve in effect at the time of grant.

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(10) Stock option plan (continued)

The assumptions used and the calculated fair values of the options issued from June 1, 2012 (inception) through December 31, 2012, were as follows:

	<u>Pool A</u>	<u>Pool B</u>	<u>Pool C</u>
Expected dividend yield	0%	0%	0%
Risk-free interest rate	0.51%	0.25%	0.17%
Weighted average expected life in years	4	2	1
Expected volatility factor	35%	35%	35%
Weighted average fair value of options granted	\$0.15	\$0.01	\$0.00001

The following is an analysis of options to purchase shares of the Company's stock issued and outstanding:

	<u>Total Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Term</u>
Total options outstanding, June 1, 2012	-	\$ -	
Granted	<u>145,271</u>	\$ 100	
Total options outstanding, December 31, 2012	145,271	\$ 100	2.32 years
Granted	-		
Exercised	-		
Expired/cancelled	<u>-</u>		
Total options outstanding, December 31, 2013	<u>145,271</u>	\$ 100	1.46 years
Total options exercisable, December 31, 2013	<u>11,041</u>	\$ 100	

A summary of the status of the Company's nonvested options as of December 31, 2013 and 2012, and changes during 2013 and 2012, is presented below:

Nonvested options	<u>Options</u>	<u>Weighted Average Grant-Date Fair Value</u>
Nonvested, June 1, 2012	-	\$ -
Granted	145,271	0.06
Vested	<u>-</u>	<u>-</u>
Nonvested, December 31, 2012	145,271	0.06
Granted	-	
Vested	<u>(11,041)</u>	<u>0.06</u>
Nonvested, December 31, 2013	<u>134,230</u>	<u>\$ 0.06</u>

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(11) Related-party transactions

On June 1, 2012, the Company entered into three Management Services Agreements with companies related to certain preferred stockholders to perform certain services for the Company, including consulting, financial analysis, marketing, and general support services as reasonably requested by the Board of Directors. The contracts are for a term of ten years with annual payments due of \$600,000, payable quarterly. The expense under these agreements approximated \$600,000 and \$350,000 for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, respectively; however, the payment of the management fee has been suspended in connection with the restructuring of the long-term debt on December 31, 2012 (see Note 7). Interest on unpaid management fees will accrue at an annual rate of 6.0% compounded monthly. As of December 31, 2013 and 2012, \$631,543, and \$150,000 is payable to the related party, respectively. Interest expense for the year ended December 31, 2013 was \$31,543. There was no interest expense for the period from June 1, 2012 (inception) through December 31, 2012. In connection with the acquisition (see Note 2), the Company recorded approximately \$333,000 as a receivable in prepaid and other current assets for expenses paid by the Company on the seller's behalf. The Company was paid by the seller in 2013 after the escrow related to the sale was settled.

(12) Retirement plan

The Company has a contributory profit sharing plan, as defined under Section 401(k) of the U.S. Internal Revenue Code, covering substantially all employees. During the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, the Company made contributions to this plan at a rate of 3% of the participating employees' compensation. Company contributions are subject to a vesting schedule. The employee becomes 100% vested with respect to the employer contributions after completing six years of service. Employer contributions during the year ended December 31, 2013 and for the period of June 1, 2012 (inception) through December 31, 2012, were approximately \$381,000 and \$180,000, respectively.

(13) Income taxes

The income tax benefit for the year ended December 31, 2013 and for the period from June 1, 2012 (inception) through December 31, 2012, consisted of the following:

	<u>2013</u>	<u>2012</u>
Current income taxes (benefit)		
Federal	\$ 1,533,843	\$ (201,400)
State	398,270	76,122
	<u>1,932,113</u>	<u>(125,278)</u>
Deferred income tax benefit		
Federal	(2,359,215)	(6,420,644)
State	(476,635)	(1,453,265)
	<u>(2,835,850)</u>	<u>(7,873,909)</u>
Total income tax benefit	<u>\$ (903,737)</u>	<u>\$ (7,999,187)</u>

Included in the 2012 deferred tax benefit above is approximately \$6,300,000 related to the impairment of the tradenames (see Note 3).

PENTEC HEALTHCARE INFUSIONS, INC. & SUBSIDIARIES

NOTES TO FINANCIAL STATEMENTS

(13) Income taxes (continued)

Deferred income taxes reflect the effect of temporary differences between the carrying amounts of the assets and liabilities for financial reporting purposes and the carrying amounts used for income tax reporting purposes. Significant components of the Company's deferred tax assets and liabilities as of December 31, 2013 and 2012 are as follows:

	<u>2013</u>	<u>2012</u>
Current deferred tax assets (liabilities):		
Accounts receivable reserves	\$ 711,797	\$ 993,154
Inventory	49,747	37,504
Accrued expenses	1,582,096	464,754
Federal benefit of state deferred	(114,788)	(75,508)
Prepaid assets	(70,417)	-
Total current deferred tax assets	<u>2,158,435</u>	<u>1,419,904</u>
Long-term deferred tax assets (liabilities):		
Book basis in excess of tax - intangible assets	(43,322,091)	(45,558,971)
Federal benefit of state deferred, net of current portion	2,139,780	2,276,866
Tax basis in excess of book - depreciation	250,423	292,436
Interest rate cap	39,538	-
Total long-term deferred tax liabilities	<u>(40,892,350)</u>	<u>(42,989,669)</u>
Net deferred income taxes	<u>\$ (38,733,915)</u>	<u>\$ (41,569,765)</u>

(14) Industry conditions

As part of ongoing business operations, the Company and its customers are subject to legislative and regulatory changes that may impact operations and the level of reimbursement received from third-party payors, including Medicare and certain private payors. The Company's reimbursement is determined by agreements that the Company negotiates with those payors or their benefit manager representatives. Due to the changing political and healthcare climate, the termination or modification of the agreements could affect the Company's reimbursement from these sources. These changes could have a material effect on the Company's results of operations and cash flows and its ability to repay the Company's obligations. Given the current reimbursement landscape, the Company continues to add sales personnel and expand the Company's market penetration, improve operational efficiencies, and reduce costs to mitigate the impact on results of operations, where possible. As presented in the accompanying consolidated financial statements, the Company increased annualized revenues and cash flows from operations. The Company has been in compliance with its financial covenants, which are monitored by the Company on a regular basis. Also, over the past two years, the Company has agreed to new reimbursement rates with the Company's two largest payor groups, representing over 50% of consolidated net revenues. None of the Company's other payors represent more than 10% of the consolidated net revenues. Subsequent to December 31, 2013, the Company received a written communication from the U.S. Food and Drug Administration ("FDA") as a follow up to the FDA's inspection of the Company during the year ended December 31, 2013. The Company has provided the FDA with its written response within the requested timeframe. The Company has not yet received any additional communication from the FDA.

(15) Subsequent events

Subsequent events have been evaluated through June 26, 2014, the date these consolidated financial statements were available to be issued.

ATTACHMENT

SECTION C, ECONOMIC FEASIBILITY, ITEM 6.A

Home Infusion Fee Schedule, Pentec Health, Inc.

HOME INFUSION FEE SCHEDULE

CODE	DESCRIPTION	Charge
S9328	Home infusion therapy, implanted pump pain management infusion; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	\$100.00
S9363	Home infusion therapy, antispasmodic therapy; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	\$80.00
S9338	Immunotherapy - IVIG administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	\$175.00
S9490	Corticosteroid-(Solumedrol) administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem	\$135.00
S9379	Infusion therapy, not otherwise classified	\$100.00
S9364	TPN < 1 Liter	\$175.00
S9365	TPN 1 Liter	\$185.00
S9366	TPN >1.0 – 2.0 Liters	\$280.00
S9367	TPN >2.1 – 3.0 Liters	\$300.00
S9368	TPN >3 Liters	\$320.00
99601	Home infusion/specialty drug administration, per visit (up to 2 hours);	\$225.00
99602	Home infusion/specialty drug administration, per visit (up to 2 hours); each additional hour (List separately in addition to code for primary procedure)	\$112.50
SS	HOME INFUSION SERVICES PROVIDED IN THE INFUSION SUITE OF THE IV THERAPY PROVIDER	N/A
SD	SERVICES PROVIDED BY REGISTERED NURSE WITH SPECIALIZED, HIGHLY TECHNICAL HOME INFUSION TRAINING	N/A
SH	SECOND CONCURRENTLY ADMINISTERED INFUSION THERAPY	N/A

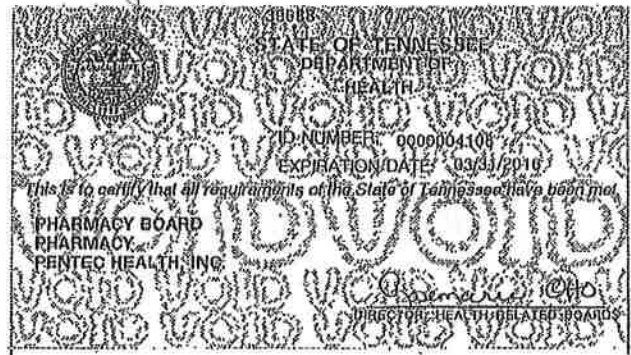
MISCELLANEOUS INTRATHECAL FEE SCHEDULE

CODE	DESCRIPTION	CHARGE
A4220	Refill Kit for Implantable Infusion Pump	\$60.00
95990	Re-filling and maintenance of implantable pump	\$400.00
62368	Analysis with re-programming of Intrathecal Pump	\$200.00
62367	Analysis without re-programming of Intrathecal Pump	\$150.00
98969	E-Visit by Non-Physician Healthcare Provider for Established Patients	\$45.00
98966	Telehealth Visit by NON-Physician 5-10 minutes	\$15.00
98967	Telehealth Visit by Non-Physician 11-20 minutes	\$30.00
98968	Telehealth Visit by Non-Physician 21-31 minutes	\$45.00
99366	Medical team conference with interdisciplinary team of health care professionals, face-to-face with patient and/or family, 30 minutes or more, participation by nonphysician qualified health care professional	\$55.00
99368	Medical team conference with interdisciplinary team of health care professionals, patient and/or family not present, 30 minutes or more; participation by nonphysician qualified health care professional	\$45.00

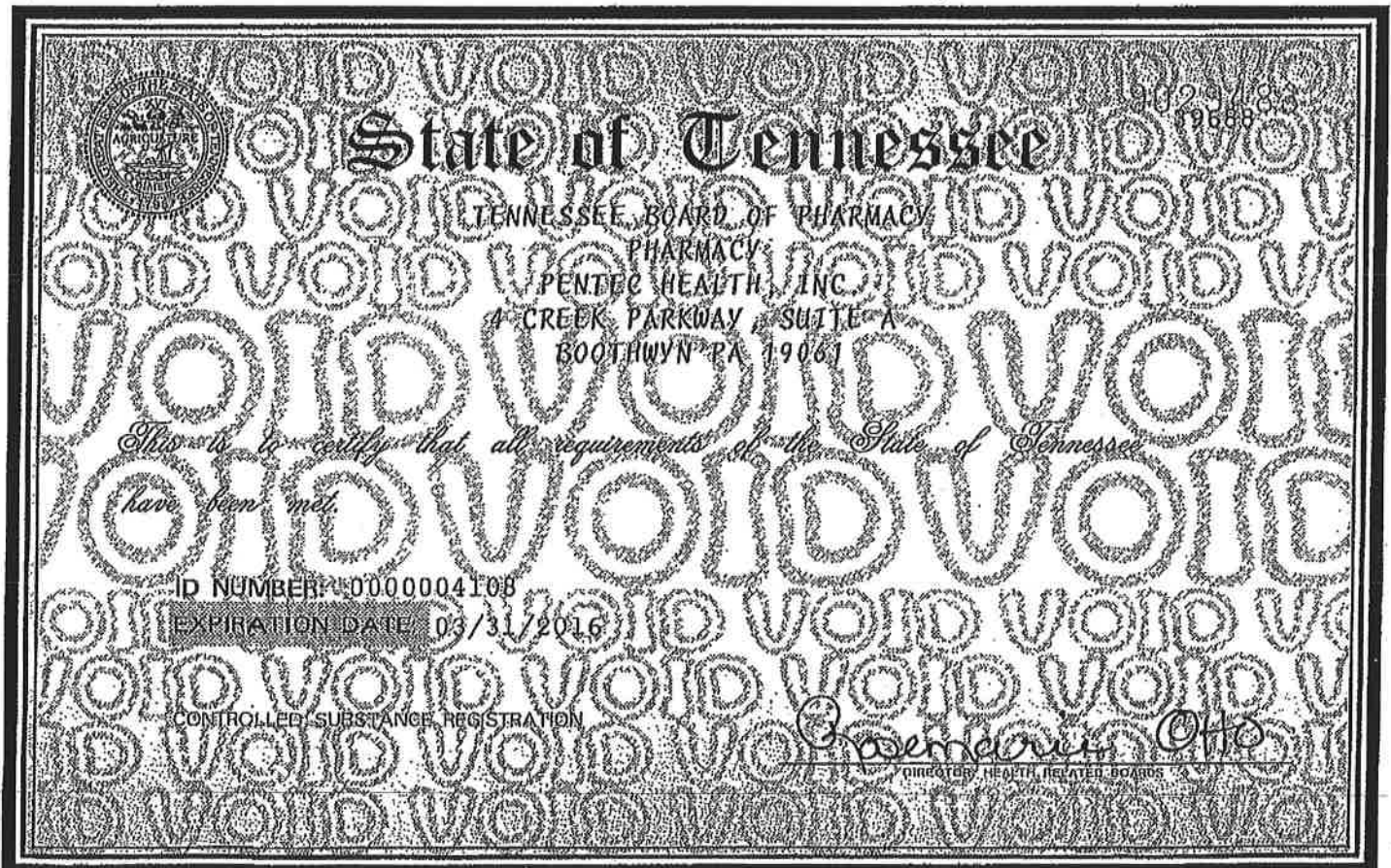
ATTACHMENT

**SECTION C, CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF
HEALTH CARE, ITEM 7.c**

1. Tennessee Pharmacy License, Pentec Health, Inc.
2. Accreditation Certificate and Letter from The Joint Commission, Pentec Health, Inc.



PHARMACIST-IN-CHARGE
PENTEC HEALTH, INC.
4 CREEK PARKWAY, SUITE A
BOOTHWYN PA 19061-3132



Pentec Health, Inc.

Boothwyn, PA

has been Accredited by



The Joint Commission

Which has surveyed this organization and found it to meet the requirements for the
Home Care Accreditation Program

June 7, 2014

Accreditation is customarily valid for up to 36 months.

Rebecca J. Patchin MD

Rebecca J. Patchin, MD
Chair, Board of Commissioners

Organization ID #10297

Print/Reprint Date: 06/30/2014

Mark R. Chassin MD, FACP, MPP, MPH

Mark R. Chassin, MD, FACP, MPP, MPH
President

The Joint Commission is an independent, not-for-profit national body that oversees the safety and quality of health care and other services provided in accredited organizations. Information about accredited organizations may be provided directly to The Joint Commission at 1-800-994-6610. Information regarding accreditation and the accreditation performance of individual organizations can be obtained through The Joint Commission's web site at www.jointcommission.org.



October 9, 2014

Joe Cosgrove
Chief Executive Officer
Pentec Health, Inc.
4 Creek Parkway, Suite A
Boothwyn, PA 19061

Joint Commission ID #: 10297
Program: Home Care Accreditation
Accreditation Activity: Measure of Success
Accreditation Activity Completed: 10/09/2014

Dear Mr. Cosgrove:

The Joint Commission would like to thank your organization for participating in the accreditation process. This process is designed to help your organization continuously provide safe, high-quality care, treatment, and services by identifying opportunities for improvement in your processes and helping you follow through on and implement these improvements. We encourage you to use the accreditation process as a continuous standards compliance and operational improvement tool.

The Joint Commission is granting your organization an accreditation decision of Accredited for all services surveyed under the applicable manual(s) noted below:

- Comprehensive Accreditation Manual for Home Care

This accreditation cycle is effective beginning June 07, 2014. The Joint Commission reserves the right to shorten or lengthen the duration of the cycle; however, the certificate and cycle are customarily valid for up to 36 months.

Please visit Quality Check® on The Joint Commission web site for updated information related to your accreditation decision.

We encourage you to share this accreditation decision with your organization's appropriate staff, leadership, and governing body. You may also want to inform the Centers for Medicare and Medicaid Services (CMS), state or regional regulatory services, and the public you serve of your organization's accreditation decision.

Please be assured that The Joint Commission will keep the report confidential, except as required by law. To ensure that The Joint Commission's information about your organization is always accurate and current, our policy requires that you inform us of any changes in the name or ownership of your organization or the health care services you provide.

Sincerely,



Mark G. Pelletier, RN, MS
Chief Operating Officer
Division of Accreditation and Certification Operations



Accreditation Quality Report

- > Summary of Accreditation Quality Information
- > Accredited Programs
- > Accreditation National Patient Safety Goals
- > Sites and Services
- > Accreditation History
- > Download Accreditation PDF Report
- > Accreditation Quality Report User Guide

Symbol Key

- The organization has met the National Patient Safety Goal.
- The organization has not met the National Patient Safety Goal.
- The goal is not applicable for this organization.

Quality Report

Summary of Accreditation Quality Information



Pentec Health, Inc.
Org ID: 10297
4 Creek Parkway, Suite A
Boothwyn, PA 19061
(484)480-2222
www.pentechealth.com

Accreditation Programs	Accreditation Decision	Effective Date	Last Full Survey Date	Last On-Site Survey Date
<u>Home Care</u>	<u>Accredited</u>	6/7/2014	6/6/2014	6/6/2014

Accreditation programs recognized by the Centers for Medicare and Medicaid Services (CMS)
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

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National Patient Safety Goals and National Quality Improvement Goals

Compared to other Joint Commission Accredited Organizations

		Nationwide	Statewide
Home Care	2014 National Patient Safety Goals		*

* State results are not calculated for the National Patient Safety Goals.

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Sites and Services

* Primary Location

An organization may provide services not listed here. For more information refer to the [Quality Report User Guide](#).

Locations of Care

Diversified Management Services-
DBA: Pentec Health, LLC
1722 Ninth Street
Wichita Falls, TX 76301

Available Services

Services:

- Home Health, Non-Hospice Services
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Integrated Neurology Services, LLC-VA office
DBA: Pentec Health, LLC
7115 Leesburg Pike Suite 201
Falls Church, VA 22043

Services:

- Home Health, Non-Hospice Services
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Pain Consultants of Alabama, LLC
DBA: Pentec Health, LLC
7101 US Highway 90, Suite 192
Daphne, AL 36526

Services:

- Home Health, Non-Hospice Services
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Pain Rehabilitation Group of Wichita Falls, TX
DBA: Pentec Health

Services:

- Home Health, Non-Hospice Services

4301 Maplewood Avenue Suite
A
Wichita Falls, TX 76308

- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Pentec Health
DBA: Pentec Health
14301 First National Bank
Parkway,
Omaha, NE 68154

Pentec Health, Illinois
5600 North River Road, Suite
800
Rosemont, IL 60018

Pentec Health, Inc
DBA: Pentec Health, Inc
1615 Poydras Street, Suite 900
New Orleans, LA 70112

Pentec Health, Inc
DBA: Pentec Health
950 Bannock Street, Suite 1100
Boise, ID 83702

Pentec Health, Inc
DBA: Pentec Health
9393 West 110th Street, 51
Corporate Woods, Suite 500
Overland Park, KS 66210

Pentec Health, Inc
DBA: Pentec Health
14301 First National Bank
Omaha, NE 68154

Pentec Health, Inc
DBA: Pentec Health
1915 NW AmberGlen, 4th Floor
Beaverton, OR 97006

Pentec Health, Inc
DBA: Pentec Health
220 North Main Street, Suite
500
Greenville, SC 29601

Pentec Health, Inc
DBA: Pentec Health
222 S. Main Street, 5th Floor
Salt Lake City, UT 84101

Pentec Health, Inc
DBA: Pentec Health
1201 Pacific Avenue, 6th floor
Tacoma, WA 98402

Pentec Health, Inc
DBA: Pentec Health, Inc
232 Market Street
Flowood, MS 39232

Pentec Health, Inc
DBA: Pentec Health, Inc
300 International Drive, Suite
100
Buffalo, NY 14221

Pentec Health, Inc
DBA: Pentec Health, Inc
2700 Corporate Drive, Suite 273
Birmingham, AL 35242

Services:

- Home Health, Non-Hospice Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Pentec Health, Inc
DBA: Pentec Health, Inc
10955 Westmoor Drive, 4th
floor
Broomfield, CO 80021

Pentec Health, Inc.
DBA: Pentec Health
609 SW 8th Street, 6th floor
Bentonville, AR 72712

Pentec Health, Inc.
DBA: Pentec Health Inc.
120 Forbes Boulevard
Mansfield, MA 02048

Services:

- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Pentec Health, Inc.
DBA: Pentec Health, Inc
250 Monroe NW, Suite 400
Grand Rapids, MI 49503

Pentec Health, Inc., Boothwyn,
PA *
4 Creek Parkway, Suite A
Boothwyn, PA 19061

Services:

- Durable Medical Equipment
- External Infusion Pumps and/or Supplies
- Home Health, Non-Hospice Services
- Implanted Infusion Pumps and Supplies
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

Pentec Health, Indiana
48 N. Emerson Avenue, Suite
300, Office #240
Greenwood, IN 46143

Pentec Health, Iowa
305 2nd Avenue SE Suite 200
Cedar Rapids, IA 52401

Pentec Health, Minnesota
DBA: Pentec Health
Fifth Street Towers 100 South
Fifth Street, Suite 1900
Minneapolis, MN 55402

Pentec Health, North Carolina
Landfall Executive Suites, 1213
Culbreth Drive, Suite 140
Wilmington, NC 28405

Pentec Health, Texas
18756 Stone Oak Parkway,
Suite 200
San Antonio, TX 78258

Tampa Pain Relief Center, Inc.
DBA: Pentec Health, Inc
100 West Gore Street, Suite 500
Orlando, FL 32806

Services:

- Home Health, Non-Hospice Services
- Pharmacy, Clinical Consulting Services
- Pharmacy/Dispensary, General Services
- Skilled Nursing Services

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The Joint Commission obtains information about accredited/certified organizations not only through direct observations by its employees [...Read more.](#)

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ATTACHMENT

**SECTION C, CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF
HEALTH CARE, ITEM 8**

1. Order, Indiana State Department of Health, *In re the Matter of Pentec Health, Inc.*
2. Letter Accepting Plan of Correction of Pentec Health, Inc., Indiana State Department of Health

ORDER

WHEREFORE, the Director, pursuant to the Health Commissioner's determination that violations have occurred, **ORDERS** Pentec Health, Inc. to pay a civil penalty totaling Ten thousand dollars (\$10,000.00) to the Indiana State Department of Health. Payment of the imposed civil penalty should be made payable to the Indiana State Department of Health and may be submitted to:

Indiana State Department of Health
Attn: Cashier's Office
2 North Meridian Street, Suite 2-C
Indianapolis IN 46204-3006

If Pentec Health, Inc. wishes to seek administrative review and/or a stay of effectiveness of this *Notice of Citation* pursuant to Ind. Code §4-21.5-3-6(d) and §4-21.5-3-2(e), it must petition the State Health Commissioner, in writing, within eighteen (18) days after this Notice of Citation is mailed to Pentec Health, Inc. The petition must include facts demonstrating that:

- a. the petitioner is the person to whom the Order is specifically directed;
- b. the petitioner is aggrieved or adversely affected by the Order; and
- c. the petitioner is entitled to review under any law.

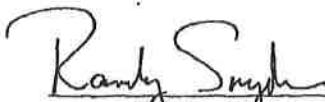
If no petition for review or stay of effectiveness is timely filed, this Order becomes a FINAL ORDER at that time.

Any petition for review and/or petition for stay of effectiveness must be submitted in writing to:

Indiana State Department of Health
Attn: Office of Legal Affairs
2 North Meridian Street, Suite 3-H
Indianapolis, IN 46204-3006

So ORDERED this 22nd day of August, 2011.

INDIANA STATE DEPARTMENT OF HEALTH
DIVISION OF ACUTE CARE



Randy Snyder, Director
Division of Acute Care



Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

CMS CERTIFICATION Number (CCN):
MEDICAID VENDOR Number:
FACILITY Number: 012608

October 17, 2011

Karen McHenry
Administrator
Pentec Health Inc
4 Creek Parkway, Suite A
Boothwyn, PA 19061

RE: Event ID: 6FVZ11

Dear Karen McHenry:

On October 5th, 2011 the Division of Acute Care received your Plan of Correction in response to the Initial State Licensure survey on August 10, 2011 of Pentec Health Inc. The Plan of Correction you submitted has been found to be acceptable.

Sincerely,

Kelly Hemmelgarn, BSN, RN
PHNSS-Program Director
ISDH/Acute Care Division
317/233/7541

SUPPLEMENTAL
#1

November 25, 2014

9:50 am

PENTEC HEALTH, INC.

SUPPLEMENT NO. 1

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

NOVEMBER 2014

November 25, 2014**9:50 am****1. Filing of the Application**

Please review page 3 of the application form, specifically the **FILING THE APPLICATION** section. The application as submitted should be formatted in to follow the manner discussed where answers to each question are provided in the body of the application. Only attachments supporting the answers should be provided and labeled as such.

Applications should have all pages numbered. All attachments should be attached to the back of the application, be identified by the applicable item number of the application, and placed in alpha-numeric order consistent with the application form.

Specific to Section A, please enter all Section A responses on the form with attachments placed as described in the preceding paragraph. Specific to Sections B. and C., please answer all questions on 8 ½" x 11" white paper, clearly typed and spaced, identified correctly and in the correct sequence. In answering, please type the question and the response (the applicant's use of bold font for the questions is appreciated). Please add the attachments as described in the first paragraph above.

Please submit a revised application that follows the guidelines provided above.

Pentec's application as submitted has been reformatted in the manner described above and has been submitted simultaneously with this Supplement No. 1.

November 25, 2014**9:50 am****2. Section A, Item 6**

Please identify the size, in square feet, of the office, the number of occupants that will use the office and provide a brief comparison of the rental rate to other similar professional office space in Nashville. Please also compare the \$8,028 lease rate in the Project Cost Chart to the estimated fair market value (FMV) of the space (prorated for the size of the space to be leased). This comparison is necessary in order to confirm that the cost used in the chart is the higher amount per Agency Statute. Documentation of the office space's FMV from the owner/landlord would be appreciated with your response.

Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. The office itself contains 87 square feet. In addition, Pentec and its visitors also have the use of the office suite common areas, including the Business Lounge, Refreshment Bar, Videoconferencing Room and restrooms. Excluding restrooms and the receptionist's area, this common area contains approximately 1,200 square feet.

The annual rental for Pentec's 87 square foot office is \$8,028, which equals an annual rate of \$92.28 per square foot. However, as noted above, this rate includes the use of office suite common areas, and also includes utilities, telephone lines, internet service, a shared receptionist, business and IT support, covered parking and secure 24-hour access.

Estimates of fair market rent for Class A office space in downtown Nashville vary. However, the average asking rent for 2014 has been reported at \$23.10 per square foot by Colliers International / Nashville, a member company of Colliers International Property Consultants. The "Nashville Office Market Snapshot" report for Third Quarter 2014 by Cassidy Turley, published by the *Nashville Post* on October 1, 2014, states that quoted rates for new Class A office buildings in downtown Nashville are \$33.00 - \$35.00 per square foot.

Because of the amenities included in Pentec's annual rent, a direct comparison to fair market rental rates for Class A office space in downtown Nashville is difficult. However, based on current estimates of fair market rent for Class A office space in downtown Nashville it is reasonable to conclude that Pentec's actual rent expense as shown in the Project Costs Chart is higher than the FMV rate.

3. Section A, Applicant Profile, Item 13

Why has the applicant decided not to provide intrathecal pump home infusion and immunoglobulin-G replacement therapy services (Ig-G services) to TennCare/Medicare enrollees? Is the service a covered service by these payors? Please discuss.

Pentec has already contracted with TennCare as a pharmacy (and DME) provider, although the products supplied at present relate only to Pentec's Renal Nutrition services, and not to its Specialty Infusion services. The intrathecal pump services for which Pentec would seek reimbursement from the patient's insurer has four components: medication; nursing services; supplies; and "per diem". As indicated in its answer to Section C, Need, Item 1.a.6 of Pentec's application, regarding proposed charges, Pentec estimates that average billed cost per visit for an intrathecal pump patient would be \$2,471, which includes medication (\$588), nursing services (\$71), supplies (\$37) and per diem (\$1,775). Medicare and TennCare would cover medication and may cover supplies, but would not cover nursing services or per diem. Although Pentec frequently receives less than full reimbursement from payors, it would not be able to cover the cost of providing the service to TennCare or Medicare enrollees without reimbursement for per diem. (A list of services covered by the per diem charge is attached to this Supplement as Attachment to Question 3.)

Please clarify if TennCare and/or Medicare enrollees will be provided infusion services as out-of-network or under some other arrangement.

Pentec provides services to the medically indigent under its Compassionate Care, No Insurance Coverage and Financial Assistance Policies, which are discussed in greater detail its application at Section C, Economic Feasibility, Item 9.

Services provided to TennCare and Medicare enrollees would be in-network, but for the reason noted above, Pentec cannot cover the cost of providing these services with the reimbursement that is available under these programs.

Since the applicant does not plan to seek Medicare/TennCare provider certification, where would enrollees be referred for its services? If a home health provider is not located, would an enrollee be referred back to his/her personal physician for infusion services, including pump refills? Please clarify.

If a means of coverage cannot be identified, a TennCare enrollee would be referred back to his or her personal physician, either for services or for the physician's referral to another agency. If necessary, a Pentec nurse could perform the nursing services in the office of the treating physician if the physician is unable to do so. However, as noted above, Pentec accepts traditional fee-for-service Medicaid (and Medicare) patients on a limited, compassionate care basis pursuant to existing policies that would be implemented in Tennessee. Approximately 3% of Pentec's nationwide patient census is comprised of compassionate care patients for which no reimbursement is received. Approximately 61% of its total patient census is comprised of patients for which Pentec receives compensation for some services rendered, but not all.

November 25, 2014**9:50 am**

In other parts of the application, the applicant states that home health patients in Tennessee have limited, if any, access to intrathecal pump home infusion services and Ig-G replacement therapy services. Given the applicant's existing licensed pharmacy operations in Tennessee how have its intrathecal pump patients been receiving skilled nursing services over the past several years? Please clarify.

At present, Pentec has no intrathecal pump patients in Tennessee, and its pharmacy does not deliver intrathecal medications to Tennessee.

Pentec operates a closed-door compounding pharmacy with two locations: one at its headquarters in Boothwyn, Pennsylvania, and the other in Mansfield, Massachusetts. The pharmacy is appropriately licensed in all 50 states, including Tennessee, and the District of Columbia. Pentec's pharmacy operations in Tennessee are presently limited to Renal Nutrition. Pentec's pharmacy provides renal nutrition products (and limited DME) to patients in Tennessee. These patients are typically treated in traditional renal dialysis settings, rather than in the home.

4. Section B, Project Description, Item I

Please provide responses for each item that follows:

- A. Please describe the process planned for compounding/preparation, shipping, delivery and safeguard of medications. Please describe who will be receiving the medications and the method of safeguarding shipment of same. Please also identify the name, address, license #, etc. of the pharmacy that will support the proposed Pentec HHA in Tennessee.**

Pentec operates a closed-door, specialty, sterile compounding pharmacy with locations in Boothwyn, Pennsylvania and Mansfield, Massachusetts. The pharmacy is accredited by The Joint Commission and recognized as a Center of Excellence through Dynalab's Continuous Quality Improvement Program.

Every Pentec-dispensed medication starts with an individual prescription from a physician. There are multiple steps involved in the transformation of a physician's order to the end product that reaches a patient. The pharmacy is responsible for dispensing, compounding, clinical consulting and the delivery/shipping process. Every prescription is reviewed by Pentec pharmacists to ensure the following: correct dose, frequency, diluent, concentration, stability and compatibility. Medications are always prepared in an ISO Class 5 environment using strict aseptic technique to minimize any chance of contamination. Pentec compounded sterile products ("CSPs") are custom-prepared to meet the individual needs of each patient.

A detailed description of the quality assurance measures employed by Pentec's pharmacy is attached to this Supplement as Attachment to Question 4.A.

Shipping of medication from the Pentec pharmacy is scheduled in conjunction with the next scheduled patient visit through use of Pentec's electronic medical records and scheduling system. Coordinated scheduling ensures that medication is shipped shortly before it needs to be delivered and administered. All shipments of medication are packed by a registered pharmacist at the Pentec pharmacy in a cooled, sealed and tamper-proof box. In addition to the medication, the box contains syringes that will be used to administer the medication, which are protected by tamper-proof caps, and a sharps disposal container for safe and proper disposal of used syringes. The box is accompanied by a shipping manifest that includes patient name, delivery date, physician, nurse, and medication description; and three signature lines that indicate: (i) that the box was packed and checked by a Registered Pharmacist, (ii) that the box was delivered/shipped, and (iii) that it was received by the nurse. Actual shipping is by a Pentec driver or by Federal Express. The nurse verifies that the contents of the box match the shipping manifest, and then either faxes or scans / emails the signed manifest to Pentec's Specialty Infusion staff, who deliver it to the Pentec pharmacy. The Pentec pharmacy then matches its copy of the shipping manifest with the copy returned by the nurse.

In some instances, the Pentec nurse will deliver the medication to the patient and administer the medication on the day of receipt. However, if the nurse receives the medication in advance, he or she will place the medication and syringes in a small locked box that is then placed in a refrigerator for temperature control. The box requires a key to be opened. The nurse will be instructed by Pentec during his or her orientation

3. Section B, Project Description, Item I

Please include a brief summary of the applicant's organizational structure in the executive summary, including method for oversight by the governing body.

Pentec Health, Inc. is a Pennsylvania business corporation that was organized in 1983. Its *ownership* structure is described and depicted in the Attachment, Section A, Applicant Profile, Item 4, at pages 100-102 of Pentec's revised CON application.

Pentec is *organized* into two principal operating divisions: Specialty Infusion (which includes home health care operations) and Renal Nutrition. Both the Specialty Infusion and the Renal Nutrition divisions are headed by Robert Provonche, Executive Vice President, who reports directly to Pentec's President, CEO and Board Chairman, Joseph Cosgrove. Pentec also operates a closed-door, specialty pharmacy that supports the Specialty Infusion and Renal Nutrition divisions by compounding and supplying drugs for intrathecal delivery and renal nutrition products. Pentec's pharmacy operations are headed by Barbara Knightly, Vice President, Pharmacy, who also reports directly to the President and CEO. Pentec's nursing services, which primarily support the Specialty Infusion division, are headed by Karen McHenry, R.N., M.S.N., Vice President, Nursing Services, who reports directly to the President and CEO. Financial management of Pentec, including the Specialty Infusion division, is under the direction of Art Rea, the Chief Financial Officer. An executive-level organizational chart is attached to this Supplement No. 2 as Attachment to Question 3.

The Board of Directors provides oversight of Pentec in accordance with the requirements of Pennsylvania law. The Board has regular meetings on a quarterly basis and special meetings as needed; and also takes action in between meetings by unanimous written consent. In addition, the President and CEO (who is also Chairman of the Board of Directors) has telephone contact with various Board members on an almost-daily basis.

In addition, Pentec's nurse management team (including the Vice President of Nursing Services and the Regional Nurse Managers) meets on a weekly basis to discuss HHA matters. Information from this meeting is communicated to the HHA nursing staff during structured monthly meetings, and otherwise as needed.

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to purchase the box and will be reimbursed by Pentec. On the day of the patient visit, the medication and syringes will be removed from the box, placed in a delivery bag for transportation, and taken by the nurse to the patient's treatment location for administration. Depending on the outside air temperature, the delivery bag will be placed in an insulated container to be kept cool or to avoid freezing during transport. Upon arrival at the patient's treatment location, the nurse will take the delivery bag inside. The contents will be removed and a delivery ticket will be signed by the patient (or caregiver, if applicable). The medication will then be administered by the nurse.

Pentec's Pennsylvania pharmacy would support operations in Tennessee. The pharmacy is owned by Pentec Health, Inc., and it is located at 4 Creek Parkway, Boothwyn, Pennsylvania 19061. Its Pennsylvania pharmacy license number is PP413743L, and its Tennessee pharmacy license number is 4108.

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4. B. Should a patient served by Pentec require home health services for conditions other than those related to the intrathecal pump home infusion products, how does the applicant intend to respond to these needs across all counties of Tennessee based on a staff of one registered nurse in Year 1? Will these services be provided directly by the applicant's nursing staff or will the applicant seek to refer the patient out to another licensed home health agency to provide the skilled nursing care not related specifically to the infusion service?

Services will be coordinated with, and patients will be referred to, another licensed agency that can meet the other needs that patients may have not related to home infusion services. Pentec's nurse case manager will assist the patient, his or her family, and caregivers, with community resources if the need is identified. Pentec's assigned primary care nurse ensures that referrals are made as necessary, initiates and continues communication and coordination of care with others involved, and ensures the established plan of care is known and implemented in collaboration with the attending physician.

For budgeting and financial projection purposes, Pentec has allocated 1.2 FTE nurses to Tennessee for the first year of operation. However, this does not necessarily mean that one full-time nurse would be responsible for treatment of all Tennessee patients. Pentec nurses based in Kentucky, Virginia and North Carolina who are also licensed to practice in Tennessee could be assigned to specific patients, depending on location. Pentec anticipates that additional nursing staff based in Tennessee would be hired as the patient census increases. Given that patients typically require one visit every 30-60 days, statewide coverage has not proved to be a problem in any state in which Pentec operates.

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4. C. Please define specific types of services patients are likely to require and discuss what special needs and care the patient and/or caregiver will require for the proposed skilled nursing intrathecal pump and Ig_G replacement therapy services. In your response, please identify those the minimum skilled nursing activities that must be provided as a condition of HHA licensure in Tennessee such as taking & recording patient vital signs and drawing blood and other fluids for lab tests.

The services that Pentec proposes to offer would be very limited. The primary service provided would be skilled nursing services for complex patients with severe, chronic pain or spasticity who have failed traditional therapy and who now rely on intrathecal pumps for drug delivery. As an ancillary service, Pentec would also offer immunoglobulin-G replacement therapy services, by either IV or subcutaneous infusion, to patients whose immune systems are compromised. The skilled nursing activities required in connection with treatment of these patients include:

1. Knowledge of medications administered/instilled/infused including common side effects, any possible adverse reactions, and actions to implement if an adverse reaction occurs; and educating patients, their families and caregivers with respect to the same.
2. Accessing various intrathecal pumps using supplies in appropriate kits provided by the particular intrathecal pump manufacturer.
3. Use of programmer with certain types of intrathecal pumps. (When use of a programmer is required, items that can be programmed can include medication changes and adjustments.)
4. Assessing intrathecal and intravenous access sites and surrounding areas for possible complications.
5. Taking and recording vital signs.
6. Collecting blood specimens when ordered by physician.
7. Establishing peripheral intravenous access for intravenous Ig-G infusion when patient does not present with long term access already in place.
8. Knowledge and use of an anaphylaxis kit with intravenous Ig-G when needed.
9. Basic life support: cardiopulmonary resuscitation.

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4. D. Please clearly identify the responsibilities of the patient's physician, the pharmacy that will be contracted to support the HHA's specialty infusion services (including compounding pharmacy, if applicable), the home health agency (including administrator, director of nurses and home infusion RN), and any others associated with the care of the patient for intrathecal pump and Ig-G services.

The patient's physician will refer the patient to Pentec for treatment, order the patient's plan of care, and prescribe all medication to be provided to the patient. In addition, the physician will review the patient's plan of care at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

Because Pentec operates a closed-door specialty pharmacy with particular expertise in the preparation and compounding of the medications prescribed for Pentec patients, it will not be contracting with another pharmacy. Rather, Pentec's pharmacy will supply all medication required by Tennessee patients directly.

The responsibilities and required qualifications of the Administrator of the Tennessee HHA are set forth in a written job description, a copy of which is attached to this Supplement as Attachment to Question 4.D. The Administrator will designate in writing a qualified alternate who will act in the absence of the Administrator. The responsibilities and required qualifications of Pentec primary care nurses are also set forth in a written job description, a copy of which is also attached in Attachment to Question 4.D.

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4. E. Has the applicant collaborated with existing HHAs and state professional HHA association(s) to identify and assess the need for its specialty IP and Ig-G services? Were any existing service providers identified in the assessment? If so, why aren't these arrangements working in TN? Please describe the applicant's planning and research efforts in this regard in preparing for the development of its certificate of need application. In your response, please include any documentation from representatives indicating their participation in preparing an assessment of the need for the proposed HHA.

Pentec has not collaborated with any existing Tennessee home health agencies for intrathecal pump nursing services because no existing licensed agency has the same level of expertise in this specialized area of service. Pentec is aware that Professional Home Health provides services to intrathecal pump patients in a limited number of counties in Tennessee, and that Basic Home Infusion may also provide this service in Tennessee. Coram Specialty Infusion has the capability of providing intrathecal pump services, but recently announced its decision to discontinue this service nationally.

Pentec has contracted with commercial providers of health care market intelligence to provide data with respect to intrathecal pump use nationwide.

Pentec is aware that there are established providers of Ig-G replacement therapy in Tennessee such as Coram Specialty Infusion (in Middle Tennessee). Pentec seeks authority to provide Ig-G replacement therapy as an ancillary service, particularly to "crossover" patients who have intrathecal pumps but would also benefit from Ig-G replacement therapy. To Pentec's knowledge, no licensed agency in Tennessee provides both intrathecal pump therapy and Ig-G replacement therapy.

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4. F. The applicant is proposing a statewide, topographically diverse service area covering all rural and urban Tennessee counties. Discuss how the applicant's 1 registered nurse intends to service approximately 39 patients representing 234 skilled nursing visits in Year One statewide from a single location in Nashville focusing on a 24/7 hour response time?

For budgeting and financial projection purposes, Pentec has allocated 1.2 FTE nurses to Tennessee for the first year of operation. However, this does not necessarily mean that one full-time nurse would be responsible for treatment of all Tennessee patients. Pentec nurses based in Kentucky, Virginia and North Carolina who are also licensed to practice in Tennessee could be assigned to specific patients, depending on location. Further, Pentec anticipates that additional nursing staff based in Tennessee would be hired as the patient census increases. Given that patients typically require one visit every 30-60 days, statewide coverage has not proved to be a problem in any state in which Pentec operates. Pentec has established a target patient-to-nurse ratio of 40:1 in its operations in other states and has determined through experience that statewide coverage at that ratio is manageable, even in large states such as Texas.

Pentec recognizes that provision of services to patients throughout Tennessee may require its nurses to travel long distances. However, because of the nature of the services provided by Pentec and the patient population it serves, proximity of patients is much less important than would be the case with a traditional home care provider.

As noted above, patients must have their intrathecal pumps refilled and reprogrammed at regular intervals. Because consequences of a pump running dry are serious and sometimes life-threatening, this cannot be allowed to happen, and Pentec has implemented procedures to ensure that it does not happen. Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances. In addition, each Pentec primary care nurse (the nurse assigned to a particular patient) is backed up by one or more other nurses who are available to provide care to the primary care nurse's assigned patient if the need arises. Finally, Pentec has a sufficient number of nurses licensed to practice in Tennessee to ensure that full coverage is always available.

Additionally, all Pentec patients (and/or their representatives, if applicable) are educated on the signs and symptoms of medication withdrawal and overdose and the need to seek medical attention in such an event. In addition, Pentec nurses monitor pump battery life and advise patients in advance of the need to have the batteries replaced. (Intrathecal pumps are implanted surgically and batteries must be replaced in a surgical procedure.) However, a malfunction of an intrathecal pump is not an event that can be addressed by a Pentec contingency plan. As with any medical emergency, a patient with a malfunctioning intrathecal pump will need to seek immediate medical attention.

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4. G. Please provide brief descriptions of the following: (1) how potential diversions will be handled such as those that could involve the loss or theft of controlled substances; (2) the level of physician involvement in the provision of services to the proposed home health agency's patients; (3) the technology to be used to facilitate the nursing service across the entire state such as the use of video conferencing during in-home patient visits.

1. Diversion

Pentec has developed a shipping, storage and delivery protocol that is designed to ensure continuous Pentec custody of all medication until the time it is administered to the patient and thereby keep the risk of loss or diversion to an absolute minimum. Shipping of medication from the Pentec pharmacy is scheduled in conjunction with the next scheduled patient visit through use of Pentec's electronic medical records and scheduling system. Coordinated scheduling ensures that medication is shipped shortly before it needs to be delivered and administered. All shipments of medication are packed by a registered pharmacist at the Pentec pharmacy in a cooled, sealed and tamper-proof box. In addition to the medication, the box contains syringes that will be used to administer the medication, and these are protected by tamper-proof caps. The box is accompanied by a shipping manifest that includes patient name, delivery date, physician, nurse, and medication description; and three signature lines that indicate: (i) that the box was packed and checked by a Registered Pharmacist, (ii) that the box was delivered/shipped, and (iii) that it was received by the nurse. Actual shipping is by a Pentec driver or by Federal Express. The nurse verifies that the contents of the box match the shipping manifest, and then either faxes or scans / emails the signed manifest to Pentec's Specialty Infusion staff, who deliver it to the Pentec pharmacy. The Pentec pharmacy then matches its copy of the shipping manifest with the copy returned by the nurse.

In some instances, the Pentec nurse will deliver the medication to the patient and administer the medication on the day of receipt. However, if the nurse receives the medication in advance, he or she will place the medication and syringes in a small locked box that is then placed in a refrigerator for temperature control. The box requires a key to be opened. The nurse will be instructed by Pentec during his or her orientation to purchase the box and will be reimbursed by Pentec. On the day of the patient visit, the medication and syringes will be removed from the box, placed in a delivery bag for transportation, and taken by the nurse to the patient's treatment location for administration. Depending on the outside air temperature, the delivery bag will be placed in an insulated container to be kept cool or to avoid freezing during transport. Upon arrival at the patient's treatment location, the nurse will take the delivery bag inside. The contents will be removed and a delivery ticket will be signed by the patient (or caregiver, if applicable). The medication will then be administered by the nurse.

In the unlikely event of theft of a controlled substance during the process described above, appropriate state or local law enforcement authorities would be notified immediately. Because patient visits are scheduled well in advance of the "alarm date" described above in the answer to Question 4.F, delivery of replacement medication would be completed sufficiently far in advance to avoid any risk to the patient.

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2. Physician Involvement

The patient's physician will refer the patient to Pentec for treatment, order the patient's plan of care, and prescribe all medication to be provided to the patient. In addition, the physician will review the patient's plan of care (developed by the assigned primary care nurse with physician input) at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

Treating physicians will have 24/7 access to patient records and real-time updates following patient visits through use of Pentec's proprietary Physician Portal, located on its website, which provides physicians with secure access to patients' medical information and also allows secure, HIPAA-compliant secure, two-way videoconferencing capability ("eVisit") that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the in-home visit.

3. Technology

Pentec nurses utilize a secure HIPAA-compliant proprietary electronic medical records ("EMR") and communication system for patient care scheduling, documentation, communications, and reporting. This proprietary EMR system is purpose-built to address assessment and record keeping needs of the intrathecal pump patient. All data from a patient encounter is entered into the system by the primary care nurse to ensure accuracy and timeliness of data entry. Individual patient outcomes are recorded and tracked against the patient's plan of treatment at each encounter. All data – physical assessments, pain or Ashworth scores, pump telemetries, prescriptions, refill dates, alarm dates, etc. – are available 24/7/365 to physicians and their staff via Pentec's proprietary Physician Portal.

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- 4. H. Please discuss how the applicant intends to develop, manage, implement, supervise and maintain patients' plans of care, including plans to manage patient pain.**

The patient's plan of care is developed by the patient's primary care nurse in collaboration with the patient and his or her physician. The plan of care is implemented at the patient's start of care, and upon any changes in the patient's status or prognosis. The patient's primary care nurse manages the plan of care by initiating at the start of care and identifying and reporting any changes to the physician that could change the patient's plan of care and treatment goals. If no change to the plan of treatment is noted by the primary care nurse, the plan of care will be maintained as signed and noted during previous certification period, with renewal submitted for physician signature. Patient pain is addressed in the plan of care by intrathecal pump medications and patient treatment goals, as appropriate.

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4. I. Please identify the owner's experience in other states and identify any active licenses. Please also note the status of Medicare/Medicaid certification and accreditation. A suggested template to use is provided in the table below.

Pentec Heath Home Health and Pharmacy Licenses and Accreditation

State	Pharmacy (License #)	Home Health (License #)	Medicare and Medicaid Certified?	Accreditation?	Addresses
Alabama	112799 (Non-resident) 201458 (Mail order)	Not Required ¹	Note 4	Note 5	7101 US Hwy. 90, Suite 192 Daphne, AL 39581 2700 Corporate Dr., Suite 273 Birmingham, AL 35242
Alaska	990	NA ²	Note 4	Note 5	
Arizona	Y004336	Not Required	Note 4	Note 5	
Arkansas	OS02201	NA	Note 4	Note 5	609 SW 8th St., 6th Floor Bentonville, AR 72712
California	NRP 740	NA	Note 4	Note 5	
Colorado	5533	04L578	Note 4	Note 5	10955 Westmoor Dr., 4th Floor Westminster, CO 80021
Connecticut	PCN.0000387	Not Required	Note 4	Note 5	
District of Columbia	NRX11004418	Pending ³	Note 4	Note 5	1875 I St. NW, 5th Floor Washington, DC 20006
Delaware	A9-0001115	Not Required	Note 4	Note 5	
Florida	PH 17905	Not Required	Note 4	Note 5	100 West Gore St., Suite 500 Orlando, FL 32806
Georgia	Not Required	Not Required	Note 4	Note 5	
Hawaii	PMP-392	NA	Note 4	Note 5	
Idaho	2034MS	NA	Note 4	Note 5	
Illinois	54.017968	4000334	Note 4	Note 5	5600 N. River Rd., Suite 800 Rosemont, IL 60018
Indiana	64000300A	11-012608-1	Note 4	Note 5	48 N. Emerson Ave., Ste. 300 Greenwood, IN 46143
Iowa	3602	Not Required	Note 4	Note 5	305 2nd Avenue SE Cedar Rapids, IA 52401
Kansas	22-10406	A046221	Note 4	Note 5	9393 West 110th St., Ste. 500 Overland Park, KS 66210
Kentucky	PA1197	720358 (MHS)	Note 4	Note 5	
Louisiana	PHY.005655-OS	Not Required	Note 4	Note 5	1615 Poydras St., Suite 900 New Orleans, LA 70112
Maine	MO40001318	NA	Note 4	Note 5	
Maryland	P04099	R2565	Note 4	Note 5	
Massachusetts	Not Required	Not Required	Note 4	Note 5	120 Forbes Boulevard Mansfield, MA 02048
Michigan	5301008358	Not Required	Note 4	Note 5	250 Monroe NW, Suite 400 Grand Rapids, MI 49503
Minnesota	263902	29528	Note 4	Note 5	100 S. 5th St., Suite 1900 Minneapolis, MN 55402
Mississippi	04557/07.1	Not Required	Note 4	Note 5	232 Market Street Flowood, MS 39232
Missouri	2012025471	Not Required	Note 4	Note 5	
Montana	2232	NA	Note 4	Note 5	
Nebraska	603	HHA201312	Note 4	Note 5	14301 1st National Bank Pkwy. Omaha, NE 68154
Nevada	PH02052	NA	Note 4	Note 5	
New Hampshire	NR0140	03941	Note 4	Note 5	
New Jersey	28RO00021500	HP0082000	Note 4	Note 5	
New Mexico	PH00002805	Pending	Note 4	Note 5	100 Sun Ave. NE, Suite 650 Albuquerque, NM 87109

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State	Pharmacy (License #)	Home Health (License #)	Medicare and Medicaid Certified?	Accreditation?	Addresses
New York	26488	Pending	Note 4	Note 5	300 International Dr., Ste. 100 Williamsville, NY 14221
North Carolina	9320	HC4486	Note 4	Note 5	1213 Culbreth Drive, Ste. 140 Wilmington, NC 28405
North Dakota	560	NA	Note 4	Note 5	
Ohio	NTP.021460900	Not Required	Note 4	Note 5	
Oklahoma	99-1133	NA	Note 4	Note 5	
Oregon	RP-0002005-CS	NA	Note 4	Note 5	1915 NW Amber Glen, 4th Fl. Beaverton, OR 97006
Pennsylvania	PP413743L	Not Required	Note 4	Note 5	4 Creek Parkway Boothwyn, PA 19061
Rhode Island	PHN09809	NA	Note 4	Note 5	
South Carolina	13999	NA	Note 4	Note 5	220 N. Main St., Suite 500 Greenville, SC 29601
South Dakota	400-0600	Not Required	Note 4	Note 5	
Tennessee	4108	Pending	Note 4	Note 5	
Texas	23805	013924	Note 4	Note 5	18756 Stone Oak Parkway San Antonio, TX 78258 4301 Maplewood Ave., Ste. A Wichita Falls, TX 76308
Utah	6517607-1708	NA	Note 4	Note 5	222 S. Main St., 5th Floor Salt Lake City, UT 84101
Vermont	36.0086621	Not Required	Note 4	Note 5	
Virginia	214000859	HCO13944	Note 4	Note 5	7115 Leesburg Pike, Suite 201 Falls Church, VA 22043
Washington	PHNR.FO.00058078	NA	Note 4	Note 5	1201 Pacific Ave., 6th Floor Tacoma, WA 98402
West Virginia	MO0560330	Not Required	Note 4	Note 5	
Wisconsin	209-43	Not Required	Note 4	Note 5	
Wyoming		NA	Note 4	Note 5	

Notes:

1. Home Health License "Not Required" means that Pentec's Specialty Infusion operations in these states do not require licensure as a HHA under applicable state law.
2. Home Health License "NA" means that Pentec's Specialty Infusion division is not active in these states.
3. Home Health License "Pending":
 - a. Pentec has received a CON (No. 14-0-1) for a HHA in the District of Columbia and has submitted its HHA licensure application, which is presently under review.
 - b. Pentec has submitted HHA licensure applications in New Mexico and New York, both of which are under review.
 - c. Pentec has submitted CON application CN1411-046 in Tennessee.
4. Pentec has not sought Medicare certification for HHA services, only state licensure.
5. Pentec is accredited by The Joint Commission. Pentec's accreditation certificate and letter, and related information from The Joint Commission, is attached to its application as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c.

5. Section B, Project Description, Item II.C.

Please also briefly discuss the following:

- A) From the applicant's experience, please provide an estimate of the additional health care delivery cost savings, such as elimination of hospital stays, outpatient visits, etc., which could be realized by initiation of this new service.**

Pentec does not presently have data relating to cost savings realized to the health care system through elimination of unnecessary hospital stays, outpatient visits, ambulance transportation, and the like. However, through its experience in other states, Pentec has become familiar with situations in which substantial cost savings could be realized through implementation of the proposed services. In addition, research (discussed in Pentec's application at Section C, Need, Item 1) has shown that Among patients with pain and spasticity, average annual health plan expenditures are estimated to be \$70,000. Over half of those expenses are for inpatient encounters that may have been averted by a more comprehensive care model such as that provided by Pentec.

- B) From the applicant's experience, please discuss how the proposed service will safeguard against potential errors, such as medication errors that could result in serious harm or death.**

All nurses attend an intensive, ANCC (American Nurses Credentialing Center) certified training program upon hire. Performance Improvement initiatives focus on patient safety to ensure safe patient care. Those initiatives include, but are not limited to, root-cause analysis, safety checklist implementation, chart audits, and self-learning modules to enhance learning and promote excellent, safe, quality care. A copy of Pentec's Nurse Training Program Policy and Procedure, describing its ANCC-certified training program, is attached to this Supplement as Attachment to Question 5.B.

- C) Please describe how the governing body of the proposed HHA will monitor and enforce compliance with all patient safety standards of care that apply to the project.**

The Board of Directors of Pentec Health, Inc., its governing body, oversees all standards of care involving patient safety with direct reports from Pentec's executive team, including the Vice President of Nursing and Vice President of Pharmacy. The Board also receives direct reports from the Pharmacy and Specialty Infusion divisions quarterly as part of Pentec's ongoing corporate performance improvement process, as documented in its annual Performance Improvement Plan. In addition, the Board receives direct reports from Pentec's Corporate Compliance officer with details of process improvement initiatives and demonstrations of continued compliance. A copy of Pentec's 2014 Performance Improvement Plan is attached to this Supplement as Attachment to Question 5.C.

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5. D) Please identify any plans for the use of telemedicine to support patient care activities. What measures will be taken to ensure that the applicant and physicians participating in this service will comply with the Department of Health's Board of Medical Examiner's Rules (0880-02-.16) for registration & licensing? What measures will be taken to comply with patient confidentiality?

Pentec anticipates that its Tennessee patient referrals would come from physicians located within Tennessee, and, as such, the Telemedicine Licensure rules set forth at Section 0880-02-.16 of the Rules of the Tennessee Board of Medical Examiners would not be implicated. That said, through its experience in other states, Pentec is aware that intrathecal pump patients, in particular, are sometimes required to travel across state lines for treatment and could benefit from in-home treatment. In any such situation involving a Tennessee resident and an out-of-state physician referred to Pentec for treatment in Tennessee, Pentec would ascertain prior to the start of care, through consultation with the referring and a licensure check whether 1) the out-of-state physician is duly licensed in accordance with Section 0880-02-.06(2), or 2) one of the exemptions from licensure set forth at Section 0880-02-.06(6) applies.

In the event that an out-of-state were to use Pentec's videoconferencing capability through its Physician Portal in connection with the practice of telemedicine, the communication is secure. Pentec's eVisit platform utilizes HIPAA compliant Hypertext Transfer Protocol Secure (HTTPS) communications protocol for secure video conferencing with the patient's care team directly from a patient's home during a visit. For maximum patient confidentiality, Pentec only facilitates this service with patient, Pentec care team (nurse, pharmacist) and the patient's physician. Conferences are not recorded.

6. Section B, Project Description, Item V (Home Health Agency)

Item 4 – Please explain the rationale for a parent office without any branch offices located in the applicant’s proposed 95 county state-wide service area. What consideration was given to locating branch offices in distinct geographic areas, in order to reduce driving times or distance requirements, and ensure access to a sufficient workforce such as nursing staff for skilled nursing services?

As discussed in greater detail in the answer to Question 4.F, Pentec recognizes that provision of services to patients throughout Tennessee may require its nurses to travel long distances. However, because of the nature of the services provided by Pentec and the patient population it serves, proximity of patients is much less important than would be the case with a traditional home care provider. Pentec schedules all patient visits 7 to 10 days prior to the “alarm date” (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances. In addition, each Pentec primary care nurse (the nurse assigned to a particular patient) is backed up by one or more other nurses who are available to provide care to the primary care nurse’s assigned patient if the need arises. Finally, Pentec has a sufficient number of nurses licensed to practice in Tennessee to ensure that full coverage is always available.

Because of the nature of the services provided, Pentec nurses do not necessarily travel from an office to conduct patient visits, and Pentec has not found branch offices to be necessary in other large states. That said, Pentec has considered branch or second offices in jurisdictions with regional licensure requirements. For example, Pentec is presently considering the opening of a second office in Kansas in order to serve patients in the central part of that state.

November 25, 2014**9:50 am****7. Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services, Items 1 through 4)**

Based on the applicant's experience with home health agency operations in other states such as Alabama, Virginia, and North Carolina, please complete the table below to identify some of the key obstacles the applicant has encountered in other states:

	2012	2013
Total intrathecal pump (IP) home infusion patients	1,783	2,177
Number of IP home patients whose infusion has been delayed	0	0
Number of days of delay in initiation of IP home infusion services	0	0
Number of additional days in the hospital due to delays in initiation of IP services	NA	NA

All *initial* intrathecal pump therapy service is done by the patient's physician, Pentec does not initiate these services in a hospital setting or otherwise. Therefore, there are no delays relating to the initiation of intrathecal pump therapy services to report. Moreover, the possibility of intrathecal pump patients experiencing delays in subsequent treatment is eliminated by careful coordination of patient care with treating physicians as the key to prevention. Also, Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances occur.

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Review of the Tennessee Department of Health "Licensed Facilities" report on the Department's website revealed that there are approximately 157 home health agencies (HHA) presently licensed to serve in Tennessee.

Because the scope of the project includes the creation of a home health agency, the applicant must include all existing licensed HHAs authorized to serve the statewide service area in order to apply the need formula correctly and identify the net need for any additional agencies at this time and four years in the future (CY2018).

Please complete the table in Exhibit 1 below by identifying all licensed home health agencies, the counties they are licensed to serve, and their most recent utilization as reported to the Department of Health in the Joint Annual Report (JAR).

Exhibit 1

Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Accredo Health Group, Inc.	79456	Shelby	6 (6)	9	14	20
Advanced Home Care, Inc.	82051	Sullivan	8 (8)	2,825	2,583	2,245
Advanced Home Care, Inc.	30021	Greene	4 (4)	385	526	762
Alere Women's and Children's Health, LLC	33423	Hamilton	13 (13)	18	52	74
Alere Women's and Children's Health	79466	Shelby	7 (7)	357	401	417
Alere Women's and Children's Health, LLC	19654	Davidson	14 (14)	140	196	202
Amedisys Home Health	67024	Overton	11 (11)	1325	1277	1453
Amedisys Home Care	26054	Franklin	15 (15)	1015	1074	1150
Amedisys Home Care	79146	Shelby	3 (3)	882	938	1060
Amedisys Home Health	19674	Davidson	14 (14)	2834	2943	5182
Amedisys Home Health	90121	Washington	6 (6)	2496	2384	1821
Amedisys Home Health	33103	Hamilton	19 (19)	3358	3342	2878
Amedisys Home Health	79386	Shelby	4 (4)	2411	1806	1934
Amedisys Home Health	75054	Rutherford	7 (7)	543	554	661
Amedisys Home Health Care	47202	Knox	27 (27)	5267	5420	5354
Amedisys Home Health Care	57075	Madison	19 (19)	2489	2586	2741
Amedisys Home Health Care	10031	Carter	7 (7)	1241	1147	1171
Amedisys Home Health Care	75064	Rutherford	17 (17)	1476	1431	1582
Amedisys Home Health Care	32102	Hamblen	13 (13)	3613	3675	3896
Amedisys Home Health Care	79246	Shelby	3 (3)	576	683	936
Amedisys Home Health of Tennessee	13022	Claiborne	5 (5)	1730	2074	1830
Amedisys Home Health Svcs.	19684	Davidson	10 (10)	756	388	23
Americare Home Health Agency, Inc.	79256	Shelby	2 (2)	1324	1727	1811

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Baptist Home Care and Hospice - Covington	84046	Tipton	5 (5)	326	361	353
Baptist Memorial Home Care	09065	Carroll	11 (11)	235	213	262
Baptist Trinity Home Care	79276	Shelby	3 (3)	3248	3367	3862
Baptist Trinity Home Care - Private Pay Division	79446	Shelby	1 (1)	1	1	1
Best Nurses, Inc.	79546	Shelby	3 (3)	311	366	364
Blount Memorial Hospital Home Health Services	05012	Blount	19 (19)	1357	1308	1224
C.M.C. Home C.A.R.E.	18054	Cumberland	1 (1)	536	409	407
Camellia Home Health of East Tennessee, LLC	47062	Knox	22 (22)	1448	1556	1716
CareAll	19724	Davidson	21 (21)	-	-	1562
Careall Home Care Services	89074	Warren	8 (8)	520	337	637
CareAll Home Care Services	47232	Knox	6 (6)	257	278	510
CareAll HomeCare Services	84076	Tipton	14 (14)	1491	1103	1556
CareAll Home Care Services	92025	Weakley	12 (12)	1903	2668	2036
CareAll HomeCare Services	60074	Maury	11 (11)	285	224	609
Caresouth HHA Holdings of Winchester, LLC	26024	Franklin	35 (35)	1395	1371	2030
Suncrest Home Health	13032	Claiborne	11 (11)	436	581	852
Clinich River Home Heath	01032	Anderson	7 (7)	473	468	461
Continucare Healthservices, Inc. - I	33213	Hamilton	8 (8)	1638	1494	1466
Continucare Healthservices, Inc. - II	33383	Hamilton	11 (11)	21	17	8
Continuous Care Services, LLC	19664	Davidson	6 (6)	905	671	407
Coram Specialty Infusion Services	19734	Davidson	37 (37)	-	-	11
Covenant HomeCare	47402	Knox	16 (16)	3838	3946	3953
Cumberland River HomeCare	14024	Clay	10 (10)	361	236	392
Deaconess HomeCare II	36025	Hardin	11 (11)	1213	1244	1330
Deaconess HomeCare	76032	Scott	5 (5)	406	352	394
Deaconess HomeCare	52024	Lincoln	24 (24)	712	704	842
Deaconess HomeCare	95034	Wilson	21 (21)	1237	1210	1222
East Tennessee Children's Hospital Home Health Care	47222	Knox	16 (16)	671	559	586
Extended Health Care, Inc.	79136	Shelby	6 (6)	780	341	79
Elk Valley Health Services, LLC	19494	Davidson	95 (95)	250	245	277
Lifeline of West Tenn., LLC	57095	Madison	20 (20)	962	993	1085
Extendicare Home Health Care of Union City, LLC	66035	Obion	5 (5)	398	347	302
Family Home Care, Cleveland	06043	Bradley	5 (5)	673	1023	598
Family Home Health Agency	79206	Shelby	1 (1)	375	863	379
Friendship Home Health, Inc.	89084	Warren	10 (10)	1025	1345	1724
Friendship Home Healthcare, Inc.	19614	Davidson	14 (14)	1040	1093	845

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Angel Private Duty and Home Health, Inc.	19714	Davidson	24 (24)	10	73	123
Functional Independence Home Care, Inc.	79496	Shelby	3 (3)	729	804	953
Gateway Home Health, Clarksville	63034	Montgomery	7 (7)	1050	1067	949
Gentiva Health Services	19084	Davidson	12 (12)	1239	1239	1003
Gentiva Health Services	47042	Knox	16 (16)	898	870	779
Gentiva Health Services	16024	Coffee	9 (9)	726	629	424
Gentiva Health Services	33093	Hamilton	12 (12)	487	268	328
Gentiva Health Services	82061	Sullivan	9 (9)	1286	979	936
Gentiva Health Services	95074	Wilson	15 (15)	1705	1482	1380
The Home Option by Harden Health Care	47372	Knox	8 (8)	0	1	29
Girling Health Care, Inc.	47182	Knox	18 (18)	1093	1031	1467
Guardian Home Care of Nashville, LLC	94074	Williamson	15 (15)	1265	1365	1370
Guardian Home Care, LLC	33083	Hamilton	9 (9)	2179	2116	1484
Hancock County Home Health Agency	34011	Hancock	4 (4)	297	323	463
Henry County Medical Center Home Health	40075	Henry	5 (5)	355	399	363
Heritage Home Health	02024	Bedford	6 (6)	282	280	241
Hickman Community Home Care, Inc.	41034	Hickman	7 (7)	146	134	214
Highland Rim Home Health Agency	71014	Putnam	7 (7)	555	495	574
HMC Home Health, LLC	36035	Hardin	5 (5)	252	274	341
Home Care of Chattanooga	33133	Hamilton	3 (3)	208	119	269
Home Health Care of East Tennessee, Inc.	06063	Bradley	17 (17)	4764	4755	3318
Home Health Care of Middle Tennessee, LLC	19584	Davidson	14 (14)	4246	3914	2963
Home Health Care of West Tennessee, Inc.	79486	Shelby	4 (4)	1308	1118	1010
Health at Home	94094	Williamson	1 (1)	63	50	58
Homechoice Health Services	79376	Shelby	6 (6)	2887	1788	861
Hometown Home Health Care, Inc.	37021	Hawkins	3 (3)	173	-	89
Innovative Senior Care Home Health	19504	Davidson	22 (22)	73	504	677
Interim Healthcare of Memphis, Inc.	79056	Shelby	3 (3)	720	889	769
Intrepid USA Healthcare Services	62052	Monroe	15 (15)	238	259	358
Intrepid USA Healthcare Services	71084	Putnam	8 (8)	244	341	327
Intrepid USA Healthcare Services	79226	Shelby	4 (4)	662	615	605
Intrepid USA Healthcare Services	57165	Madison	15 (15)	294	86	422
Intrepid USA Healthcare Services	19364	Davidson	11 (11)	644	920	766
Intrepid USA Healthcare Services	89064	Warren	11 (11)	650	159	822

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Johnson County Home Health	46031	Johnson	3 (3)	403	396	446
Laughlin Home Health Agency	30041	Greene	5 (5)	553	547	655
Home Care Solutions	19544	Davidson	46 (46)	2192	2080	1930
Home Care Solutions	33363	Hamilton	10 (10)	727	734	663
Life Care at Home of Tennessee	33303	Hamilton	10 (10)	616	989	956
Lifeline Home Health Care	74064	Robertson	5 (5)	289	336	428
Lincoln Medical Home Health and Hospice	52044	Lincoln	7 (7)	356	396	348
Magnolia Regional Health Center Home Health and Hospice Agency	96010	Unknown	2 (2)	1000	915	856
Maury Regional Home Services	60044	Maury	8 (8)	1188	1220	1151
Maxim Healthcare Services	33433	Hamilton	8 (8)	71	150	56
Maxim Healthcare Services, Inc.	47432	Knox	18 (18)	159	150	159
Maxim Healthcare Services, Inc.	79536	Shelby	6 (6)	103	197	155
Maxim Healthcare Services, Inc.	19704	Davidson	9 (9)	138	141	106
Medical Center Home Health, LLC	57055	Madison	14 (14)	1403	1617	1706
Medical Center Homecare Services	90091	Washington	5 (5)	2801	3118	3503
Medical Center Homecare, Kingsport	90081	Washington	7 (7)	1126	1628	1960
Memorial Hospital Home Health	33253	Hamilton	10 (10)	3469	3264	2439
Tennove Home Health	47092	Knox	14 (14)	3586	3188	3063
Methodist Alliance Home Care	79316	Shelby	3 (3)	3226	3180	3179
University of TN Medical Center Home Health Services	32122	Hamblen	10 (10)	986	1244	1327
NHC Homecare	60024	Maury	22 (22)	2212	2134	2408
NHC Homecare	27025	Gibson	12 (12)	479	625	569
NHC Homecare	54043	McMinn	8 (8)	221	183	239
NHC Homecare	24026	Fayette	8 (8)	254	217	226
NHC Homecare	75024	Rutherford	24 (24)	3007	3269	3776
NHC Homecare	90131	Washington	7 (7)	241	264	259
NHC Homecare	47012	Knox	15 (15)	575	567	613
NHC Homecare	33033	Hamilton	10 (10)	199	203	354
NHC Homecare	74054	Robertson	6 (6)	867	909	1332
No Place Like Home, Inc.	79506	Shelby	3 (3)	38	55	58
Premier Support Services	32132	Hamblen	16 (16)	972	900	1169
Premiere Home Health, Inc.	19374	Davidson	1 (1)	118	81	87
Procure Home Health Services	30051	Greene	6 (6)	418	384	433
Professional Case Management of Tennessee	01042	Anderson	11 (11)	127	182	164
Professional Home Health Care Agency, Inc.	96030	Unknown	2 (2)	3021	2985	2641
American National Home Health	95084	Wilson	9 (9)	217	358	311
Quality First Home Care	60084	Maury	5 (5)	906	855	923

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Quality Home Health	25044	Fentress	13 (13)	4540	4012	3404
Quality Private Duty Care	25034	Fentress	9 (9)	599	703	879
Regional Home Care Parkway	96020	Unknown	1 (1)	31	14	28
Regional Home Care, Jackson	57085	Madison	15 (15)	1206	1061	1164
Regional Home Care, Lexington	39035	Henderson	22 (22)	578	616	569
Regional Home Care, Dyersburg	23035	Dyer	6 (6)	744	814	707
Senior Services Home Health	79106	Shelby	1 (1)	642	697	609
Smoky Mountain Home Health and Hospice, Inc.	15032	Cocke	12 (12)	1622	1535	1296
Still Waters Home Health Agency	79526	Shelby	1 (1)	105	127	101
Highpoint Homecare	80064	Smith	8 (8)	312	280	377
Highpoint Homecare	83114	Sumner	6 (6)	978	738	855
Sunbelt Homecare	07032	Campbell	7 (7)	285	260	261
SunCrest Home Health	21024	DeKalb	7 (7)	1406	1501	1568
SunCrest Home Health	19324	Davidson	12 (12)	5428	6710	5490
SunCrest Home Health of Manchester, Inc.	16034	Coffee	15 (15)	988	1114	1588
SunCrest Home Health of Nashville, Inc.	63044	Montgomery	6 (6)	229	381	587
Sweetwater Hospital Home Health	62062	Monroe	5 (5)	462	569	613
Tennessee Quality Homecare -- Northwest	03025	Benton	15 (15)	1129	1128	1164
Tennessee Quality Homecare - Southwest	20045	Decatur	15 (15)	1352	1082	1080
Unicoi County Home Health	86051	Unicoi	1 (1)	246	209	206
University of TN Medical Center Home Care Services - Home Health	47132	Knox	15 (15)	2530	3264	3439
Vanderbilt Community and Home Services	19394	Davidson	7 (7)	1179	1230	1879
Vanderbilt Home Care Services	19314	Davidson	7 (7)	1180	1268	1812
Volunteer Home Care, Inc.	27085	Gibson	13 (13)	2549	3027	3041
Volunteer Homecare of West Tennessee, Inc.	20055	Decatur	13 (13)	1598	1503	1534
Vanderbilt HC Affiliated Walgreens IV and RT Services	94084	Williamson	33 (33)	81	86	67
Where The Heart Is, Inc.	24036	Fayette	3 (3)	253	271	116
Willowbrook Home Health Care Agency, Inc.	19694	Davidson	36 (36)	3088	2149	1565
Willowbrook Visiting Nurse Association, Inc.	79236	Shelby	6 (6)	473	533	479
Woods Home Health, LLC	54083	McMinn	4 (4)	297	349	283

* Please highlight any HHA in bold font that offers intrathecal home infusion services, even if on a limited basis.

** Please show the # of all counties for each HHA. The # of counties in the applicant's service area should be shown separately in the bracket.

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Please complete the Exhibit 2 below identifying the estimated need in each county of the applicant's proposed statewide service area. The response should incorporate the need estimate prepared by TDH that is attached with this questionnaire. A suggested template to be used for the response is noted in the table below.

Exhibit 2
Home Health Need Formula in the Applicant's 95-County Service Area

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Tennessee	1,619	1,457	175,924	6,528,014	0.0269	6,833,509	184,157	102,503	(81,654)
Anderson	22	19	2,893	76,182	0.0380	77,851	2,956	1,168	(1,789)
Bedford	20	19	1,120	46,700	0.0240	50,566	1,213	758	(454)
Benton	11	10	667	16,315	0.0409	16,104	658	242	(417)
Bledsoe	10	8	462	12,698	0.0364	12,599	458	189	(269)
Blount	18	18	2,507	126,809	0.0198	135,171	2,672	2,028	(645)
Bradley	16	14	2,021	102,235	0.0198	107,481	2,125	1,612	(512)
Campbell	21	18	1,715	41,163	0.0417	42,566	1,773	638	(1,135)
Cannon	19	16	423	14,013	0.0302	14,540	439	218	(221)
Carroll	13	13	1,246	28,213	0.0442	27,831	1,229	417	(812)
Carter	12	11	2,072	57,228	0.0362	57,680	2,088	865	(1,223)
Cheatham	24	25	772	39,603	0.0195	40,765	795	611	(183)
Chester	14	13	563	17,355	0.0324	17,999	584	270	(314)
Claiborne	19	15	2,002	32,457	0.0617	33,280	2,053	499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673	249	115	(133)
Cocke	16	14	1,467	36,330	0.0404	38,615	1,559	579	(980)
Coffee	20	16	1,874	53,784	0.0348	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0369	14,683	541	220	(321)
Cumberland	15	13	1,601	57,370	0.0279	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0230	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0542	12,080	655	181	(473)
DeKalb	21	16	469	18,918	0.0248	19,125	474	287	(187)
Dickson	25	24	1,617	50,596	0.0320	51,964	1,661	779	(881)
Dyer	11	10	1,671	38,205	0.0437	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0178	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0346	42,122	1,459	632	(828)
Gibson	15	14	1,924	50,748	0.0379	52,163	1,978	782	(1,195)
Giles	12	11	1,001	29,325	0.0341	29,285	1,000	439	(560)
Grainger	22	20	886	22,994	0.0385	23,675	912	355	(557)
Greene	20	17	2,454	69,888	0.0351	71,594	2,514	1,074	(1,440)
Grundy	18	16	529	13,396	0.0395	13,293	525	199	(326)
Hamblen	19	17	2,835	63,763	0.0445	65,570	2,915	984	(1,932)
Hamilton	16	16	8,038	345,447	0.0233	353,577	8,227	5,304	(2,924)
Hancock	14	11	682	6,652	0.1025	6,640	681	100	(581)
Hardeman	17	15	917	26,492	0.0346	26,067	902	391	(511)
Hardin	16	14	1,157	25,968	0.0446	26,244	1,169	394	(776)

SUPPLEMENTAL #1**November 25, 2014****9:50 am**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Hawkins	21	18	2,148	57,273	0.0375	58,164	2,181	872	(1,309)
Haywood	15	13	612	18,199	0.0336	18,009	606	270	(335)
Henderson	14	13	1,015	28,080	0.0361	28,631	1,035	429	(605)
Henry	10	10	1,283	32,595	0.0394	32,956	1,297	494	(803)
Hickman	18	17	725	24,393	0.0297	24,698	734	370	(364)
Houston	12	11	281	8,358	0.0336	8,447	284	127	(157)
Humphreys	16	14	803	18,488	0.0434	18,561	806	278	(528)
Jackson	12	11	402	11,355	0.0354	11,495	407	172	(235)
Jefferson	20	19	1,749	53,006	0.0330	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
Lake	6	5	325	9,795	0.0332	9,468	314	142	(172)
Lauderdale	14	11	857	27,465	0.0312	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0394	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0332	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0313	35,697	1,116	535	(580)
Loudon	23	21	1,572	50,356	0.0312	53,192	1,661	798	(863)
McMinn	17	17	1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315	101,001	3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256	28,992	743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomery	19	20	2,903	184,087	0.0158	200,561	3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216	22,004	476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	(141)
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256	16,588	425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)

SUPPLEMENTAL #1**November 25, 2014****9:50 am**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Stewart	10	10	339	13,436	0.0252	13,941	352	209	(143)
Sullivan	14	13	5,259	158,451	0.0332	161,136	5,348	2,417	(2,931)
Sumner	26	27	4,160	169,409	0.0246	183,406	4,504	2,751	(1,753)
Tipton	26	22	1,298	63,001	0.0206	67,545	1,392	1,013	(378)
Trousdale	16	14	431	8,046	0.0536	8,582	460	129	(331)
Unicoi	13	11	659	18,334	0.0359	18,511	665	278	(388)
Union	21	18	371	19,231	0.0193	19,605	378	294	(84)
Van Buren	12	11	240	5,456	0.0440	5,474	241	82	(159)
Warren	20	15	2,266	40,299	0.0562	41,155	2,314	617	(1,697)
Washington	16	14	4,181	128,537	0.0325	138,370	4,501	2,076	(2,425)
Wayne	11	9	640	16,887	0.0379	16,724	634	251	(383)
Weakley	13	11	1,180	38,255	0.0308	39,491	1,218	592	(626)
White	14	9	962	26,612	0.0361	27,974	1,011	420	(592)
Williamson	32	32	2,815	198,045	0.0142	223,333	3,174	3,350	176
Wilson	28	31	3,727	121,626	0.0306	133,357	4,086	2,000	(2,086)

*Most recent year of Joint Annual Report data for Home Health Agencies

**Data is projected four years from the year the Home Health data was finalized, not the actual year of Home Health data.

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8. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

The applicant notes that letters of support will be provided. In addition to letters from physicians, written support from other referral sources such as hospitals and HHAs, and patients would be helpful. Please note the following:

A. *The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.*

Pentec's regional manager for Specialty Infusion with responsibility for Tennessee has called on physicians and other referral sources throughout Tennessee, and is in the process of obtaining the required letters. These will be provided as a supplement as soon as available.

B. *The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.*

As noted above, these will be provided as a supplement as soon as available.

November 25, 2014**9:50 am****9. Section C. Need, Item 1 (Specific Criteria: Home Health Services - Items 6a and 6b)**

Based on the response, it appears that a billed cost for 39 intrathecal pump patients would amount to approximately \$578,214.00 in Year 1 of the project (\$2,471 per visit x average of 6 visits per patient x 39 patients). However, the Projected Data Chart on page 18 of the application identifies \$304,573.00 in gross revenue. What accounts for the significant difference between these amounts?

The gross revenue amount of \$304,573 in the Projected Data Chart is based on a Year 1 **average** patient census of 20.2 intrathecal pump patients, not 39 patients. Pentec projects that the intrathecal pump patient census would be 5 at the beginning of Year 1 and would increase to 39 by the **end** of Year 1.

The applicant intends to charge and file claims for IP services to commercial payors and managed care organizations. Given Pentec's existing pharmacy activities in TN, what is the applicant's experience with reimbursement for intrathecal pump and Ig-G covered services in Tennessee? How does this level of reimbursement compare to allowable charges covered by Medicare for Medicare patients who receive IP home infusion and/or Ig-G services?

Pentec's pharmacy operations in Tennessee are presently limited to Renal Nutrition. Pentec's pharmacy provides renal nutrition products (and limited DME) to patients in Tennessee. However, at present, Pentec has no intrathecal pump patients in Tennessee, and its pharmacy does not deliver intrathecal medications to Tennessee. Pentec also has no Ig-G replacement therapy patients in Tennessee. Consequently, Pentec does not have experience with reimbursement for medication used in connection with these therapies, or for the services themselves, in Tennessee.

However, Pentec is aware from its experience in other states that the levels of reimbursement by commercial insurers vs. the federal Medicare and state Medicaid programs are very different for infusion services. Currently, Medicare does not cover the administration of Ig-G replacement therapy in the home, and requires that a pump be used for administration (unless delivery is subcutaneous), but does not cover the pump equipment or the nursing services; only the drug is reimbursable. The same is applicable for to intrathecal pump refills, as only the drug and the administration kit (a syringe and other low-cost disposable items) are reimbursable by Medicare. Overall, reimbursement is approximately 25% of what commercial payors who recognize the HIPAA standard code sets allow.

November 25, 2014**9:50 am****10. Section C, Need, Item 3**

This question asks applicants to identify and justify the reasonableness of the proposed service area.

What is the source of the data supporting the applicant's estimate of 1,976 intrathecal pump patients and 1,020 Ig-G patients in Tennessee as noted on page C.II.2 of the application? Using this estimate, please justify the statewide service area by providing a breakout of patients by patient county of residence for the first year of the project.

Pentec has contracted with a commercial provider of health care market intelligence that is the source of the number of intrathecal pump patients (1,876) in Tennessee. The estimated number of Ig-G replacement therapy patients in Tennessee was calculated on the basis of population and national usage of immunoglobulin-G. This calculation assumes that Tennessee represents approximately 2% of national usage of 55 million grams of Ig-G per year. This amount would be 1.1 million grams per year, or 91,667 grams per month. Assuming use of 90 grams per month per patient, Pentec arrives at the estimate of 1,020 patients.

Per telephone conversation with Mr. Grimm on November 19, 2014, Pentec is providing an estimated breakout of intrathecal pump patients for the first year of the project by Grand Division. Because Ig-G replacement therapy would be offered as an ancillary service, Pentec has assumed for purposes of its projections that no Ig-G patients would be on service in Year 1.

Grand Division	# of Intrathecal Pump patients	# of Ig-G patients
East Tennessee	17	0
Middle Tennessee	14	0
West Tennessee	8	0
Total	39	0

Using current and projected population data from the Department of Health; and the most recent enrollee data from the Bureau of TennCare and demographic information from the US Census Bureau, complete the following table and include data for each county in your proposed service area:

Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Tennessee	6,588,698	6,649,438	0.9%	6,588,698	6,649,438	0.9%	100.0%	36.7	\$44,140	1,241,028	18.8%	1,139,845	17.3%
Anderson	76,579	76,949	0.5%	76,579	76,949	0.5%	1.2%	36.7	\$44,154	14,289	18.7%	12,789	16.7%
Bedford	47,368	48,099	1.5%	47,368	48,099	1.5%	0.7%	36.7	\$39,635	11,025	23.3%	8,953	18.9%
Benton	16,257	16,208	-0.3%	16,257	16,208	-0.3%	0.2%	36.7	\$33,663	3,528	21.7%	3,316	20.4%
Bledsoe	12,641	12,610	-0.2%	12,641	12,610	-0.2%	0.2%	36.7	\$31,388	2,890	22.9%	2,920	23.1%
Blount	128,368	129,973	1.3%	128,368	129,973	1.3%	2.0%	36.7	\$46,347	19,380	15.1%	16,303	12.7%
Bradley	103,308	104,364	1.0%	103,308	104,364	1.0%	1.6%	36.7	\$40,614	18,850	18.2%	18,389	17.8%
Campbell	41,474	41,783	0.7%	41,474	41,783	0.7%	0.6%	36.7	\$31,312	11,805	28.5%	9,829	23.7%
Cannon	14,125	14,218	0.7%	14,125	14,218	0.7%	0.2%	36.7	\$40,998	2,643	18.7%	2,317	16.4%
Carroll	28,119	28,012	-0.4%	28,119	28,012	-0.4%	0.4%	36.7	\$35,595	6,895	24.5%	5,399	19.2%
Carter	57,284	57,359	0.1%	57,284	57,359	0.1%	0.9%	36.7	\$32,908	11,564	20.2%	13,061	22.8%
Cheatham	39,853	40,088	0.6%	39,853	40,088	0.6%	0.6%	36.7	\$53,363	6,453	16.2%	4,663	11.7%
Chester	17,472	17,593	0.7%	17,472	17,593	0.7%	0.3%	36.7	\$42,097	3,463	19.8%	2,953	16.9%
Claiborne	32,604	32,765	0.5%	32,604	32,765	0.5%	0.5%	36.7	\$33,568	8,121	24.9%	7,499	23.0%
Clay	7,702	7,681	-0.3%	7,702	7,681	-0.3%	0.1%	36.7	\$30,184	1,965	25.5%	1,517	19.7%
Cocke	36,762	37,207	1.2%	36,762	37,207	1.2%	0.6%	36.7	\$29,764	10,184	27.7%	9,558	26.0%
Coffee	54,273	54,817	1.0%	54,273	54,817	1.0%	0.8%	36.7	\$38,151	11,343	20.9%	11,180	20.6%
Crockett	14,596	14,611	0.1%	14,596	14,611	0.1%	0.2%	36.7	\$37,601	3,578	24.5%	2,802	19.2%
Cumberland	57,815	58,340	0.9%	57,815	58,340	0.9%	0.9%	36.7	\$37,963	10,735	18.6%	9,482	16.4%
Davidson	656,385	663,151	1.0%	656,385	663,151	1.0%	10.0%	36.7	\$46,676	124,103	18.9%	121,431	18.5%
Decatur	11,822	11,883	0.5%	11,822	11,883	0.5%	0.2%	36.7	\$34,146	2,564	21.7%	2,471	20.9%
DeKalb	18,952	18,996	0.2%	18,952	18,996	0.2%	0.3%	36.7	\$36,713	4,629	24.4%	3,601	19.0%
Dickson	50,860	51,127	0.5%	50,860	51,127	0.5%	0.8%	36.7	\$45,109	9,368	18.4%	8,138	16.0%

Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Dyer	38,218	38,246	0.1%	38,218	38,246	0.1%	0.6%	36.7	\$38,167	9,393	24.6%	7,338	19.2%
Fayette	40,930	41,835	2.2%	40,930	41,835	2.2%	0.6%	36.7	\$56,297	6,089	14.9%	5,403	13.2%
Fentress	18,404	18,553	0.8%	18,404	18,553	0.8%	0.3%	36.7	\$27,773	5,426	29.5%	4,675	25.4%
Franklin	41,230	41,391	0.4%	41,230	41,391	0.4%	0.6%	36.7	\$41,625	6,675	16.2%	6,556	15.9%
Gibson	51,102	51,412	0.6%	51,102	51,412	0.6%	0.8%	36.7	\$36,981	11,662	22.8%	9,505	18.6%
Giles	29,315	29,293	-0.1%	29,315	29,293	-0.1%	0.4%	36.7	\$38,014	5,312	18.1%	5,453	18.6%
Grainger	23,111	23,236	0.5%	23,111	23,236	0.5%	0.3%	36.7	\$33,185	5,118	22.1%	4,668	20.2%
Greene	70,187	70,520	0.5%	70,187	70,520	0.5%	1.1%	36.7	\$35,613	13,214	18.8%	15,792	22.5%
Grundy	13,355	13,322	-0.2%	13,355	13,322	-0.2%	0.2%	36.7	\$26,644	4,443	33.3%	3,873	29.0%
Hamblen	64,108	64,438	0.5%	64,108	64,438	0.5%	1.0%	36.7	\$39,316	13,519	21.1%	11,924	18.6%
Hamilton	347,451	349,273	0.5%	347,451	349,273	0.5%	5.3%	36.7	\$46,544	57,298	16.5%	56,287	16.2%
Hancock	6,652	6,645	-0.1%	6,652	6,645	-0.1%	0.1%	36.7	\$22,205	2,209	33.2%	2,175	32.7%
Hardeman	26,359	26,231	-0.5%	26,359	26,231	-0.5%	0.4%	36.7	\$31,963	6,309	23.9%	6,063	23.0%
Hardin	26,012	26,075	0.2%	26,012	26,075	0.2%	0.4%	36.7	\$33,044	6,410	24.6%	5,775	22.2%
Hawkins	57,509	57,741	0.4%	57,509	57,741	0.4%	0.9%	36.7	\$36,419	12,015	20.9%	9,431	16.4%
Haywood	18,117	18,044	-0.4%	18,117	18,044	-0.4%	0.3%	36.7	\$32,827	5,355	29.6%	3,841	21.2%
Henderson	28,186	28,279	0.3%	28,186	28,279	0.3%	0.4%	36.7	\$37,784	6,199	22.0%	4,933	17.5%
Henry	32,697	32,766	0.2%	32,697	32,766	0.2%	0.5%	36.7	\$36,593	7,157	21.9%	5,689	17.4%
Hickman	24,422	24,465	0.2%	24,422	24,465	0.2%	0.4%	36.7	\$42,330	5,462	22.4%	3,981	16.3%
Houston	8,388	8,413	0.3%	8,388	8,413	0.3%	0.1%	36.7	\$34,595	1,692	20.2%	1,820	21.7%
Humphreys	18,498	18,519	0.1%	18,498	18,519	0.1%	0.3%	36.7	\$41,943	3,605	19.5%	2,590	14.0%
Jackson	11,368	11,383	0.1%	11,368	11,383	0.1%	0.2%	36.7	\$33,363	2,581	22.7%	2,740	24.1%
Jefferson	53,729	54,482	1.4%	53,729	54,482	1.4%	0.8%	36.7	\$38,800	10,568	19.7%	10,316	19.2%
Johnson	18,094	18,090	0.0%	18,094	18,090	0.0%	0.3%	36.7	\$30,063	4,009	22.2%	4,596	25.4%
Knox	453,629	459,124	1.2%	453,629	459,124	1.2%	6.9%	36.7	\$47,270	65,007	14.3%	64,415	14.2%
Lake	9,732	9,676	-0.6%	9,732	9,676	-0.6%	0.1%	36.7	\$26,212	2,012	20.7%	2,949	30.3%
Lauderdale	27,341	27,264	-0.3%	27,341	27,264	-0.3%	0.4%	36.7	\$32,987	7,108	26.0%	7,136	26.1%

Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Lawrence	42,329	42,373	0.1%	42,329	42,373	0.1%	0.6%	36.7	\$36,663	8,905	21.0%	7,619	18.0%
Lewis	12,112	12,112	0.0%	12,112	12,112	0.0%	0.2%	36.7	\$33,956	2,567	21.2%	2,350	19.4%
Lincoln	34,281	34,624	1.0%	34,281	34,624	1.0%	0.5%	36.7	\$40,904	6,405	18.7%	5,622	16.4%
Loudon	50,926	51,495	1.1%	50,926	51,495	1.1%	0.8%	36.7	\$49,602	7,366	14.5%	7,435	14.6%
McMinn	53,233	53,476	0.5%	53,233	53,476	0.5%	0.8%	36.7	\$38,944	10,660	20.0%	9,848	18.5%
McNairy	26,582	26,755	0.7%	26,582	26,755	0.7%	0.4%	36.7	\$33,066	6,935	26.1%	6,247	23.5%
Macon	23,188	23,419	1.0%	23,188	23,419	1.0%	0.4%	36.7	\$35,452	6,061	26.1%	5,449	23.5%
Madison	99,555	99,971	0.4%	99,555	99,971	0.4%	1.5%	36.7	\$42,348	21,610	21.7%	18,219	18.3%
Marion	28,556	28,652	0.3%	28,556	28,652	0.3%	0.4%	36.7	\$39,817	6,198	21.7%	5,483	19.2%
Marshall	31,286	31,413	0.4%	31,286	31,413	0.4%	0.5%	36.7	\$40,687	5,575	17.8%	5,600	17.9%
Maury	82,280	82,526	0.3%	82,280	82,526	0.3%	1.2%	36.7	\$45,603	15,237	18.5%	13,000	15.8%
Meigs	12,205	12,331	1.0%	12,205	12,331	1.0%	0.2%	36.7	\$33,492	2,700	22.1%	2,844	23.3%
Monroe	46,092	46,563	1.0%	46,092	46,563	1.0%	0.7%	36.7	\$36,430	10,221	22.2%	8,896	19.3%
Montgomery	187,649	191,068	1.8%	187,649	191,068	1.8%	2.9%	36.7	\$49,459	25,741	13.7%	30,399	16.2%
Moore	6,350	6,364	0.2%	6,350	6,364	0.2%	0.1%	36.7	\$44,977	781	12.3%	933	14.7%
Morgan	21,848	21,870	0.1%	21,848	21,870	0.1%	0.3%	36.7	\$37,522	4,321	19.8%	4,173	19.1%
Obion	31,453	31,365	-0.3%	31,453	31,365	-0.3%	0.5%	36.7	\$40,516	6,808	21.6%	5,378	17.1%
Overton	22,489	22,593	0.5%	22,489	22,593	0.5%	0.3%	36.7	\$34,119	4,561	20.3%	4,970	22.1%
Perry	8,014	8,025	0.1%	8,014	8,025	0.1%	0.1%	36.7	\$32,101	1,887	23.5%	1,939	24.2%
Pickett	5,019	4,998	-0.4%	5,019	4,998	-0.4%	0.1%	36.7	\$34,255	1,034	20.6%	1,054	21.1%
Polk	16,604	16,570	-0.2%	16,604	16,570	-0.2%	0.2%	36.7	\$37,235	3,529	21.3%	2,956	17.8%
Putnam	77,024	78,416	1.8%	77,024	78,416	1.8%	1.2%	36.7	\$34,107	14,591	18.9%	18,563	24.1%
Rhea	33,392	33,767	1.1%	33,392	33,767	1.1%	0.5%	36.7	\$36,470	8,090	24.2%	7,480	22.3%
Roane	54,006	54,079	0.1%	54,006	54,079	0.1%	0.8%	36.7	\$43,017	10,013	18.5%	7,777	14.2%
Robertson	70,391	71,437	1.5%	70,391	71,437	1.5%	1.1%	36.7	\$52,588	11,427	16.2%	9,151	13.0%
Rutherford	293,582	302,237	2.9%	293,582	302,237	2.9%	4.5%	36.7	\$55,105	38,869	13.2%	38,166	13.0%
Scott	21,944	21,915	-0.1%	21,944	21,915	-0.1%	0.3%	36.7	\$29,161	7,177	32.7%	5,662	25.8%

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Demographic Variable / Geographic Area	Total Population-Current Year 2014	Total Population-Projected Year 2015	Total Population-% change	*Target Population-Current Year	*Target Population-Projected Year	Target Population-% change	Target Population-Projected Year as % of Total	Median Age	Median Household Income	TennCare Enrollees	TennCare Enrollees as % of Total	Persons Below Poverty Level	Persons Below Poverty Level as % of Total
Sequatchie	15,019	15,246	1.5%	15,019	15,246	1.5%	0.2%	36.7	\$33,181	3,574	23.8%	2,899	19.3%
Sevier	94,833	96,116	1.4%	94,833	96,116	1.4%	1.4%	36.7	\$43,300	16,139	17.0%	12,708	13.4%
Shelby	943,812	946,559	0.3%	943,812	946,559	0.3%	14.2%	36.7	\$46,251	234,528	24.8%	190,650	20.2%
Smith	19,618	19,771	0.8%	19,618	19,771	0.8%	0.3%	36.7	\$44,116	3,762	19.2%	3,472	17.7%
Stewart	13,549	13,659	0.8%	13,549	13,659	0.8%	0.2%	36.7	\$40,200	2,596	19.2%	2,710	20.0%
Sullivan	158,975	159,494	0.3%	158,975	159,494	0.3%	2.4%	36.7	\$40,025	28,715	18.1%	26,867	16.9%
Sumner	172,262	175,054	1.6%	172,262	175,054	1.6%	2.6%	36.7	\$55,560	24,135	14.0%	16,882	9.8%
Tipton	63,865	64,759	1.4%	63,865	64,759	1.4%	1.0%	36.7	\$51,847	11,941	18.7%	8,941	14.0%
Trousdale	8,167	8,275	1.3%	8,167	8,275	1.3%	0.1%	36.7	\$43,613	1,761	21.6%	1,078	13.2%
Unicoi	18,376	18,419	0.2%	18,376	18,419	0.2%	0.3%	36.7	\$35,415	3,644	19.8%	4,061	22.1%
Union	19,301	19,347	0.2%	19,301	19,347	0.2%	0.3%	36.7	\$33,456	4,553	23.6%	4,362	22.6%
Van Buren	5,450	5,433	-0.3%	5,450	5,433	-0.3%	0.1%	36.7	\$31,940	1,185	21.7%	1,221	22.4%
Warren	40,489	40,662	0.4%	40,489	40,662	0.4%	0.6%	36.7	\$34,008	9,600	23.7%	9,272	22.9%
Washington	130,586	132,599	1.5%	130,586	132,599	1.5%	2.0%	36.7	\$42,995	20,213	15.5%	22,591	17.3%
Wayne	16,854	16,815	-0.2%	16,854	16,815	-0.2%	0.3%	36.7	\$35,377	2,972	17.6%	3,489	20.7%
Weakley	38,522	38,790	0.7%	38,522	38,790	0.7%	0.6%	36.7	\$35,509	6,664	17.3%	7,897	20.5%
White	26,871	27,132	1.0%	26,871	27,132	1.0%	0.4%	36.7	\$34,717	6,176	23.0%	5,401	20.1%
Williamson	202,923	207,872	2.4%	202,923	207,872	2.4%	3.1%	36.7	\$91,146	9,214	4.5%	11,770	5.8%
Wilson	124,073	126,472	1.9%	124,073	126,472	1.9%	1.9%	36.7	\$61,353	15,162	12.2%	11,539	9.3%

Note:

Pentec's target population equals the total population because Pentec serves patients in all age groups. At present, Pentec's nationwide patient census is broken down by age group as follows: 0-17 years, 4%; 18-64 years, 67%; 65 years and older, 29%.

November 25, 2014**9:50 am****11. Section C, Need, Item 5**

The applicant must address the utilization of all existing home health agencies in its proposed service area. Generally speaking, the metrics provided for this question should be very similar to the utilization information you were asked to provide for HHAs in the responses to the questions pertaining to the project specific criteria for home health services.

Pentec's proposed service area is all 95 counties in Tennessee. Utilization information for all currently-licensed home health agencies in the service area is included in the answer to Question 7 in the table at Exhibit 1.

12. Section C, Need, Item 6

Please summarize the methodology used to estimate utilization and gross revenue in Year 1 by identifying all variables that apply such as total patient visits, estimated payor mix, average charge, etc).

Pentec currently services intrathecal pump patients in many other states, and therefore based all Year 1 financial information on actual results in these other states. As such, Pentec based its average charge for Year 1 based on actual averages the Company currently recognizes. The Company also applied its actual average payor mix of 50% commercial reimbursement patients and 50% Medicare/Medicaid reimbursement patients to the Tennessee Year 1 financials. Utilization is estimated to be 100% every year as the Company hires according to its patient census in order to maintain its nurse to patient ratios.

November 25, 2014**9:50 am****13. Section C, Economic Feasibility, Item 4 (Historical and Projected Data Charts)**

Please identify the number of patients or visits in Line A of both charts.

Because revenues for Pentec Health, Inc. as a whole are derived from both its Renal Nutrition and Specialty Infusion divisions, it is not possible to specify a single unit of measure for purposes of the Historical Data Chart. However, the Projected Data Chart reflects Specialty Infusion only and uses average patient census as the unit of measure.

What is the estimated number of charity patients and/or visits to be provided in Year 1?

At present, "charity care" or "free care" patients comprise approximately 3% of Pentec's nationwide patient census, or 75 out of 2,492 intrathecal pump patients. Applying this percentage to the assumed year-end patient census of 39 for Year 1, one patient in Tennessee would be a charity care or free care patient.

Pentec receives less than full reimbursement for a significant percentage of its total patient census – currently approximately 61%. For purposes of the Projected Data Chart, Pentec assumed that at the end of Year 1, 20 patients would be full-pay commercially insured patients, and 19 would be partial-reimbursement patients.

Please explain why contractual adjustments from the applicant's charges are not budgeted in Line C.1 of the charts.

Pentec does not book revenue for free care. Therefore, no provision for free care is shown in Pentec's financial statements. Pentec's financial statements are reported at the net revenue line item. Therefore, gross revenue and contractual adjustments do occur, but are not reflected on Pentec's financial statements. Pentec provided financial information for the Historical Data Chart in the application in a manner consistent with its revenue recognition and presentation practices at the net revenue level, and as reflected in its audited financial statements.

Taxes are shown as negative numbers in the 2012 and 2013 columns of the Historical Data Chart. As a result, there appears to be a math error for the net operating income shown for these periods. Please revise and submit a replacement chart.

The reporting of negative numbers for Taxes at line D.4 of the Historical Data Chart is not an error. In 2012, Pentec took an extraordinary, one-time charge for impairment of goodwill in the amount of \$46.5 million, which resulted in a net loss of \$39.3 million for 2012. In addition, Pentec experienced reimbursement rate decreases in its Renal Nutrition operations in mid-2012, and the full-year impact of those decreases resulted in a net loss of \$1.6 million in 2013. The negative numbers for Taxes shown in line D.4 reflect tax benefits relating to the net losses in 2012 and 2013.

November 25, 2014**9:50 am****14. Section C. Economic Feasibility Item 1 (Project Cost Chart)**

Your response is noted. In accordance with HSDA Rules, please confirm that the cost of the office space in line B.1 of the chart is based on the higher of the rental cost over the term of the rental agreement or the fair market value cost of the office space. The higher of the 2 amounts must be used for this chart.

As discussed in the answer to Question 2 of this Supplement, Pentec has leased an office in the Fifth Third Center, 424 Church Street, Suite 2000, Nashville, Tennessee 37219. The office itself contains 87 square feet, although Pentec and its visitors also have the use of office suite common areas, including a Business Lounge, Refreshment Bar and Videoconferencing Room, containing an additional area of approximately 1,200 square feet.

The annual rental for Pentec's 87 square foot office is \$8,028, which equals an annual rate of \$92.28 per square foot. This rate includes the use of office suite common areas, and also includes utilities, telephone lines, internet service, a shared receptionist, business and IT support, covered parking and secure 24-hour access.

Estimates of fair market rent for Class A office space in downtown Nashville vary. However, the average asking rent for 2014 has been reported at \$23.10 per square foot by Colliers International / Nashville, a member company of Colliers International Property Consultants. The "Nashville Office Market Snapshot" report for Third Quarter 2014 by Cassidy Turley, published by the *Nashville Post* on October 1, 2014, states that quoted rates for new Class A office buildings in downtown Nashville are \$33.00 - \$35.00 per square foot.

Because of the amenities included in Pentec's annual rent, a direct comparison to fair market rental rates for Class A office space in downtown Nashville is difficult. However, based on current estimates of fair market rent for Class A office space in downtown Nashville it is reasonable to conclude that Pentec's actual rent expense as shown in the Project Costs Chart is higher than the FMV rate.

November 25, 2014**9:50 am****15. Section C. Economic Feasibility Item 4**

The applicant's charges are noted. It appears the charges may include the cost of the medications provided by Pentec's licensed pharmacy. Please clarify.

Medications provided by Pentec's pharmacy are coded separately and are not reflected on the Home Infusion Fee Schedule attached to the application as Attachment, Section C, Economic Feasibility, Item 6.A.

Please provide a comparison to allowable charges covered by commercial/managed care 3rd parties and Medicare.

Medicare does not cover home infusion nursing therapies, while typical reimbursement by commercial plans for nursing services is approximately \$92 per visit of up to 2 hours. Similarly, Medicare does not cover per diem charges, while typical reimbursement by commercial plans is in the range of \$50-70 dollars per day.

November 25, 2014**9:50 am****16. Section C, Economic Feasibility, Item 9****Please complete the following chart for the proposed HHA.**

Payor	Year One Gross Revenues	As a % of total Gross Revenue
Medicare	\$21,545	7%
Medicaid/TennCare	\$21,545	7%
Commercial insurance	\$261,483	86%
Self-Pay	\$0	0%
Charity	Not reported	NA
Total	\$304,573	100%

Note: Self-Pay is reflected at \$0. Pentec does collect self-pay in the form of co-pays from patients, but that revenue is originally recorded under the patients' primary payor, and therefore captured in the insurance categories in the lines above Self-Pay.

17. Section C, Contribution to Orderly Development, Items 1 and 2

Please explain how the applicant plans to address the geographic aspects of referral coordination and build a physician referral base of sufficient size to support the economic sustainability of the HHA's skilled nursing service for intrathecal pump patients and Ig-G patients statewide.

In each state in which Pentec operates, sales account executives solicit appropriate patient referrals from treating physicians. These account executives work closely with other companies operating in this specialized area of medicine to identify physician practices who have appropriate patients for this service. In addition, Pentec has commissioned proprietary market research and has a list of targeted physicians who have patients whom are potential candidates for this service in Tennessee. Once licensed, Pentec sales personnel will meet with appropriate potential referring physicians across Tennessee and solicit referrals for appropriate patients.

Please identify and discuss the reasons that a pain management physician in Memphis would want to refer patients to a home health agency in Nashville in lieu of continuing to provide care in his/her medical office.

A pain management physician in Memphis (or any other city) typically would refer patients to a home health agency for one of three reasons: 1) a patient is at great need for at-home service due to travel burden, overarching health status, mobility issues or the enormity of caregiver burden while transporting the patient to the treating physician's office; 2) a physician wishes to discontinue providing pump-refill procedures in their normal office due to declining of reimbursement, increased overhead required to perform the procedures or the desire to reallocate office staff time to perform more profitable procedures; or 3) the physician's practice has an acute staffing situation that diminishes or ends the offices ability to continue to perform pump refills and maintenance. Currently, there are no licensed home health agencies in Tennessee that exclusively provide intrathecal pump management services. Pentec, once licensed as a HHA, would be able to provide care for appropriate patients in Tennessee for any (and all) of the reasons physicians chose to refer their patients for intrathecal pump management.

Please describe how the applicant's plans to not participate in Medicare and TennCare contributes to orderly development in Tennessee.

At current, the TennCare and federal Medicare programs do not provide reimbursement for the type of in-home nursing services provided by Pentec, and, therefore, Pentec would not receive reimbursement for those services when rendered. However, just as in other states in which Pentec operates, Pentec is prepared and willing to provide free care or partially reimbursed care for residents of Tennessee under its Compassionate Care, No Insurance Coverage and Financial Assistance Policies, which are discussed in greater detail its application at Section C, Economic Feasibility, Item 9. Pentec's willingness to accept non-paying and partially paying patients is unique in the pump management industry. Without Pentec as a provider for intrathecal pump management, TennCare and federal Medicare plan patients may not have access to home care.

November 25, 2014**9:50 am****18. Section C, Contribution to Orderly Development, Item 7.a.**

The response is noted. What accreditation for home health agencies applies to this service?

Pentec is accredited by The Joint Commission. Pentec's accreditation certificate and letter, and related information from The Joint Commission, is attached to its application as Attachment, Section C, Contribution to the Orderly Development of Health Care, Item 7.c

Home Health Agencies are required to have a process in place to assess and manage patient pain. In addition, agency regulations require physician supervision of patient care, including the plan of care (POC) developed for each patient and review by the MD at least once every 62 days or more often if severity of the patient's condition requires. Please describe how the applicant intends to comply with these patient care requirements as a condition of licensure in Tennessee.

Under Pentec's policies, the treating physician will review the patient's plan of care (developed by the assigned primary care nurse with physician input) at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

The plan of care is implemented at the patient's start of care, and upon any changes in the patient's status or prognosis. The patient's primary care nurse manages the plan of care by initiating at the start of care and identifying and reporting any changes to the physician that could change the patient's plan of care and treatment goals. If no change to the plan of treatment is noted by the primary care nurse, the plan of care will be maintained as signed and noted during previous certification period, with renewal submitted for physician signature. Patient pain is addressed in the plan of care by intrathecal pump medications and patient treatment goals, as appropriate.

November 25, 2014**9:50 am****19. Proof of Publication**

The copies of the Letter of Intent in the 15 newspapers of general circulation identified with your LOI appear to cover 92 of 95 Tennessee counties, the exception being Hancock, Perry and Van Buren Counties. Please identify the newspapers that include these counties and provide verification from the publisher that the newspaper serves as the newspaper of general circulation.

Pentec engaged the Tennessee Press Service ("TPS"), to place the legal notices containing the letter of intent in 15 Tennessee newspapers. According to Mr. Earl Goodman of TPS, Hancock and Van Buren Counties currently do not have TPA member newspapers serving those communities and could only be reached by publishing in neighboring counties, while Perry County is served by a county-wide newspaper which does not circulate outside its borders. However, two Tennessee state agencies that use TPS for publication of notices, the Department of Transportation and the Department of General Services/Department of Finance, have designated certain newspapers as region-wide publications, meaning those newspapers sufficiently cover a number of counties and satisfy the publication needs of those Tennessee agencies. Pentec placed legal notices with the letter of intent in the following papers covering the counties in question:

Hancock County: *Knoxville News Sentinel*
Van Buren County: *Chattanooga Times Free Press*
Perry County: *Nashville Tennessean*

Copies of the newspaper pages containing the legal notices are included in Pentec's application. TPS is in the process of receiving affidavits of publication from the 15 newspapers in question, and Pentec will provide those as a supplement once received.

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AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

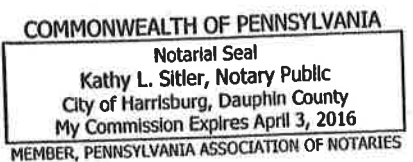
COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Joseph C. Cosgrove, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


Joseph C. Cosgrove, President and CEO

Sworn to and subscribed before me, a Notary Public, this the 21st day of November, 2014 witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.


NOTARY PUBLICMy commission expires April 3, 2016

November 25, 2014**9:50 am****ATTACHMENT TO QUESTION 3****SUPPLEMENT NO. 1**

List of services covered by the per diem charge.

pentec health

- D. Comprehensive 24 hour per day, seven days per week delivery and pick-up services. Includes mileage and the constant availability of a dedicated infusion team consisting of pharmacist(s), nurse(s), delivery team, and all other medical professionals responsible for clinical response, problem solving, trouble shooting, question answering, and other professional duties during evenings, weekends, holidays, and all other times.
- E. **Clinical Coordination. Including:**
1. Development and monitoring of nursing care plans.
 2. Coordination of benefits, care and services.
 3. Development of Patient Assessment and Patient Education materials.
 4. Coordination of non-Infusion related services.
 5. Case Management services.
 6. Measurement of Field Nursing competency with subsequent education and training.
 7. Coordination, education, training and management of Field Nursing staff (or sub-contracted agencies).
- F. **Inventories and accounts receivable. Including:**
1. Interest and opportunity costs associated with the carrying of large accounts receivable balances.
 2. Depreciation expenses.
 3. Equipment maintenance and repair.
 4. Other applicable inventory and accounts receivable expenses.
- G. **Costs associated with substantial insurance requirements.**
Includes costs associated with remaining in compliance with all state and federal regulations related to minimal insurance coverage.
- H. **Costs associated with accreditation requirements. Including:**
1. Outcomes assessments and analysis.
 2. Ongoing staff development and competency assessment.
 3. Continuous quality assessment and performance improvement programs.
 4. All other policies and procedures necessary to remain in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO), Community Health Accreditation Program (CHAP), Accreditation Commission for HealthCare (ACHC), and other professional accreditation standards.
 5. Certification fees and expenses.
 6. Other applicable accreditation expenses.
- I. **Costs associated with administrative requirements. Including:**
1. Insurance verification processes.
 2. Prior authorization requirements.
 3. Billing functions.
 4. Account Posting functions.
 5. Account collection activities.
 6. Bad debt expense.
 7. Certificate of medical necessity and other medical necessity documentation.
 8. Internal and external auditing and other regulatory compliance activities.
 9. Quality assessment and improvement activities.
 10. Professional association and subsequent fees.
 11. Other applicable administrative costs.

**SERVICES COVERED BY THE PER DIEM****A. Pharmacy Professional and Cognitive Services. Including:**

1. Initial and ongoing patient assessment and clinical monitoring.
2. Development and implementation of pharmaceutical care plans.
3. Coordination of care with physicians, nurses, patients, patient's family, other providers, and other caregivers.
4. Sterile procedures, including intravenous admixtures, clean room upkeep, vertical and horizontal laminar flow hood certification, and all other biomedical procedures necessary for a safe environment.
5. Compounding of medications.
6. Pharmacokinetic dosing.
7. Medication profile set-up.
8. Drug utilization review.
9. Comprehensive knowledge of vascular access systems.
10. Patient educational activities.
11. Monitoring of potential drug interactions.
12. Review and interpretation of patient test results.
13. Recommendation of dosage or medication changes based on clinical findings.
14. Patient discharge services, including communication with other medical professionals and closing of the medical record. Other applicable professional and cognitive services.

B. Overhead and operational expenses. Including:

1. Wages, salaries, benefits, payroll taxes, FICA, unemployment insurance, and workers compensation premiums.
2. Office supplies.
3. Sales, advertising, and marketing.
4. Physical plant expenses.
5. Utilities and telephone.
6. Cell phones and pagers.
7. Postage and shipping.
8. Patient education materials.
9. Continuing education expenses.
10. Legal and accounting expenses.
11. Licensing fees.
12. Infectious waste storage and removal.
13. Medical records storage and retrieval.
14. Community commitment and charitable donations.
15. Property Taxes.
16. New product research and development.
17. Other applicable overhead and operational expenses.

C. Infusion therapy related supplies. Including:

1. Durable, reusable infusion pumps.
2. Elastomeric, disposable infusion pumps.
3. All other infusion therapy administration devices.
4. Short peripheral vascular access devices.
5. Needles, gauze, sterile tubing, catheters, dressing kits, and other supplies necessary for the safe and effective administration of infusion therapy.
6. Other applicable supply expenses.

November 25, 2014**9:50 am****ATTACHMENT TO QUESTION 4.D****SUPPLEMENT NO. 1**

1. Job Description – Administrator (Tennessee), Pentec Health, Inc.
2. Job Description – Primary Care Nurse, Pentec Health, Inc.

November 25, 2014**9:50 am****Position Description**

Position Title: Administrator (Tennessee)

Employee Name: _____

Reports To: Vice President, Nursing

Department: Specialty Infusion

Date Prepared: _____, 20__

Approved By: Board of Directors, Pentec Health, Inc.

Date: _____, 20__

Overall Objective	The Administrator will be responsible for implementing and supervising the administrative, client care and personnel policies of the Home Health Agency ("HHA") and administratively supervising the provision of all services.
Duties and Responsibilities	<ol style="list-style-type: none"> 1. Organize and direct the HHA's ongoing operations and provision of services. 2. Act as a liaison between the HHA and the senior management and board of directors of Pentec Health, Inc. 3. Employ and, if appropriate, contract with qualified personnel. 4. Ensure adequate staff education and performance evaluations. 5. Participate in developing qualifications for assignments of personnel. 6. Ensure the accuracy of public information materials and activities, including all information pertaining to patient rights required by applicable Tennessee law. 7. Implement an effective budgeting and accounting system that promotes the health and safety of clients. 8. Ensure that the HHA meets the requirements of and remains in compliance with all applicable Tennessee statutes, rules and regulations pertaining to licensure. 9. Maintain and make available upon request to the applicable regulatory authorities, all reports, records, minutes, files, documentation and other information pertaining to the HHA in accordance with the requirements of applicable Tennessee law. 10. Ensure that a qualified alternate Administrator or other person is authorized, in writing, to act in the absence of the Administrator. 11. Implement and administer an ongoing quality assurance program designed to objectively and systematically monitor and evaluate the quality and appropriateness of client care, resolve any identified problems, and improve client care. 12. Ensure that personnel records of HHA employees who provide services

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	<p>to clients are kept current and comply with the requirements of applicable Tennessee law, and ensure that personnel policies and job descriptions are made available to all employees.</p> <p>13. Implement and participate in the development of policies and procedures consistent with standards of The Joint Commission, HIPAA and its implementing regulations, and applicable Tennessee law, and maintain copies of all applicable HHA policies and procedures.</p> <p>14. Ensure that the documentation of services provided is accurate and timely.</p> <p>15. Supervise and evaluate client satisfaction survey reports on all clients served, and ensure that all clients receive a copy of the patients' bill of rights in accordance with applicable Tennessee law.</p> <p>16. Be available in person or by telephone during normal operating hours.</p>
Authority and Accountability	Reports directly to the Vice President, Nursing. Directly supervises Nursing Supervisor (if a separate position). Supervises primary care nurses.
Skills and Competencies	<p>The Administrator should demonstrate the following competencies to perform the essential functions of this position:</p> <ol style="list-style-type: none"> 1. Have strong written and verbal communication skills along with excellent customer service skills. 2. Be a resourceful, proactive problem solver. 3. Possess strong organizational and process skills. 4. Demonstrate the ability to work well with all staff levels and with varied personalities. 5. Have the ability to work well under pressure and continually multi-task.
Education and Work Experience	<ol style="list-style-type: none"> 1. Current licensure as a Registered Nurse in Tennessee (or a compact state). 2. Possess a Bachelor of Science in Nursing (BSN) degree from an accredited School of Nursing. 3. 2+ years of clinical nursing experience. 4. 1+ years of supervisory or administrative experience in health service. 5. Strong clinical background, preferably in neurology, physical rehabilitation, pain management and/or specialty infusion. 6. Demonstrated leadership and problem solving abilities associated with the intrathecal pump. 7. Familiarity with standards of The Joint Commission for home care and a thorough understanding of HIPAA requirements. 8. Intermediate computer skills with programs such as Microsoft Office Suite: Outlook, Word, Excel and Power Point.

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Physical Demands	<p>The physical demands described here are representative of those that must be met to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.</p> <p>While performing the duties of this job, the employee is frequently required to travel via car, train or airplane; stand, sit, walk, see and hear; use hands and fingers regularly; handle or feel objects, tools, or controls; and reach with hands and arms.</p> <p>The employee must frequently lift and/or move up to 5 pounds and occasionally lift and/or move up to 40 pounds.</p>
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Signatures:

Employee

Date

Manager

Date

Human Resources

Date

November 25, 2014**9:50 am**

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Position/Title: Primary Care Nurse	Location: Field
Typical work hours:	Division:
Supervisor: Regional Nurse Manager	Department: Nursing
Employee:	Effective Date:
Wage Band:	Status: Exempt

Objective:

To administer safe infusion therapy in the home while providing quality patient care.

Critical features of this job are described under the headings below. They may be subject to change at any time due to reasonable accommodation or other reasons

Essential Duties & Responsibilities:

- Work flexible scheduled hours: days + call
- Manage all aspects of patient care including:
- Refill and reprogram intrathecal pumps
- Assess patients in all aspects of care
- Coordinate patient care with all departments
- Perform other infusion therapy as needed
- Understands and adheres to established company policies and procedures.
- Makes initial visits, processes orders, notifies physician of patient needs and changes in condition. Initiates care, completes certification/recertification orders, and discharge summaries, if required.
- Determines the amount and type of nursing needed by each individual patient.
- Regularly re-evaluates needs of the patients.
- Counsels with the patient and family/significant others on nursing, teaching and related needs.
- Inserts intravenous cannulas; administers prescribed intravenous solutions, medications, and blood products; monitors and maintains infusion sites and systems; evaluates response to prescribed therapy.
- Complies statistics as requested to quantify, qualify, and justify.
- Informs the physician and personnel of changes in the condition and needs of the patient.
- Initiates appropriate preventive and rehabilitative nursing procedures.
- Provides those services requiring substantial specialized nursing skills.
- Refers to Physical Therapist, Speech Language Pathologist, Occupational Therapist, and Medical Social Worker, Nutritionist those patients requiring their specialized skills.
- Prepares clinical records, care plans, progress notes for each patient visit and summaries of care conferences on his/her patients in a timely manner per company policy.
- Participates in in-service programs and presents in-service programs.
- Conducts patient care conferences on patients assigned to his/her care.
- Attends all patient care conferences as scheduled.
- Participates in peer review and performance improvement as assigned.
- Participates in review of clinical records as assigned.
- Takes on-call duty nights, weekends, and holidays as assigned.

November 25, 2014**9:50 am****Non Essential Duties and Responsibilities**

- Perform other duties, special projects as assigned

Skills, Competencies and Experience:**Required**

- Have strong written and verbal communication skills along with excellent customer service skills
- Be a resourceful, proactive problem solver
- Possess strong organizational and process skills
- Demonstrate the ability to work well with all staff levels and with varied personalities
- Strong clinical background.
- 2 years med/surg experience required.
- Have the ability to work well under pressure and continually multi-task

Preferred

- ICU/ER and home care experience preferred.

Education, Certifications, Trainings:**Required**

- Current licensure as a Registered Nurse and the ability to become licensed in another state if needed
- CPR certification- active

Preferred**Equipment:****Required**

- Telemetry equipment
- Intermediate computer skills with programs such as Microsoft Office Suite: Outlook, Word, Excel and Power Point

Physical requirements:

The physical demands described here are representative of those that must be met by an employee to successfully perform the essential functions of this job. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

While performing the duties of this job, the employee is frequently required to travel via car, train or plane, stand, sit, walk, see, hear, use hands and fingers regularly, handle, or feel objects, tools, or controls, and reach with hands and arms.

The employee must frequently lift and/or move up to 5 pounds and occasionally lift and/or move up to 40 pounds.

Nothing in this job description restricts management's right to assign or reassign duties and responsibilities to this job at any time.

This job description reflects management's assignment of essential functions; it does not prescribe or restrict the tasks that may be assigned.

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Pentec Health, Inc. is committed to maintaining workplaces that are free from illegal drugs, controlled substances, and/or alcohol.

By signing below I acknowledge that I have reviewed this job description with the associate listed above:

Manager/Supervisor Signature: _____ Date: _____

Employee Signature: _____ Date: _____

Human Resources Signature: _____ Date: _____

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ATTACHMENT TO QUESTION 5.B

SUPPLEMENT NO. 1

Nurse Training Program Policy and Procedure, Pentec Health, Inc.

PENTEC HEALTH, INC. AND AFFILIATED COMPANIES**INFUSION****POLICY AND PROCEDURE****1.8 NURSE TRAINING PROGRAM****PURPOSE:**

To ensure proper training for each nurse hired to maintain consistent, high quality care in the provision of services to high tech patients served by Pentec Health, Inc.. To provide each newly trained nurse with a mentor to support them through their orientation, training and professional development.

POLICY:

1. Primary Care Nurses are interviewed and selected by a Regional Nurse Manager, a member of the Training Team, and/or the Vice President, Nursing Services.
2. All Primary Care Nurses are oriented to Pentec policies and procedures by a member of the Training Team and a Regional Nurse Manager as part of their orientation. This is provided during a two week intensive classroom presentation. The first week of classroom is presented by the Regional Nurse Manager and includes general orientation to the company (see New Associate Orientation Checklist Specialty Infusion-Nursing) as well as beginning introduction to the EMR, Programmer, Refills, etc.
3. The second week of classroom presentation is given by a member of the training team. The new Primary Care Nurse is given hands on practice with the N'Vision Programmer and practice with accessing SynchroMed pumps as well as practice with the EMR system. The new PCN is introduced to the clientele serviced by Pentec Health along with the theory behind administration of intrathecal medications via an implanted pump. All trainers have completed a preceptor training program focused on adult learning.
4. Following completion of the classroom session, the new Primary Care Nurse will either spend two weeks in a high volume area (Pennsylvania or other high volume area) to do intensive access training or will return to his/her home area to start training with a Preceptor. Preceptors are experienced Primary Care Nurses who have completed the one day Preceptor Workshop. At the end of training in the high volume area, an Orientation Progress Report will be initiated via conference call.
5. The training in the home area will encompass all aspects of care including but not limited to new admissions, pump refills, pump adjustments, patient assessments, physician contact and documentation. This training will be guided by a Preceptor (if in an existing

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area with an established patient base) or a Traveler/Trainer (in an expansion area without established patients). At the end of each week, a report will be given to the Regional Nurse Manager and the Director of Education outlining the weekly progress and goals for the coming week.

6. At the completion of three months, the nurse will take a knowledge exam proctored by the Trainer or Regional Nurse Manager. The nurse must obtain a passing grade of 80%. (See Measurements of Success policy.) Remedial instruction will be given for all incorrect answers.
7. Orientation is not completed until the Preceptor/Traveler Trainer, the Director of Nursing Education and the Regional Nurse Manager are in agreement that the new Primary Care Nurse has successfully completed all areas of the "Initial Competency Tool for Nurses." Another conference call will be done at this time and an Orientation Progress Final Report will be completed. At this time a mentor will be assigned to the new PCN.
8. In the event that the Primary Care Nurse is unable to complete all aspects of the initial competency tool due to lack of exposure to those patients with the specified competency (Synchronomed EL refill/programming, advanced flex programming, medication change with bridge bolus, reservoir rinse) the skill can be demonstrated in demo mode/simulation and can be marked as a demonstrated competency from that. When the nurse then encounters the actual situation she will notify the Regional Nurse Manager and discuss the procedure prior to seeing the patient.
9. Primary Care Nurses shall follow the job description for the Primary Care Nurse as outlined by Pentec Health.
10. The Regional Nurse Manager will attempt to visit onsite a minimum of once yearly for the purpose of performance evaluations. When possible, the Regional Nurse Manager will "ride along" and observe the Primary Care Nurse while she performs her duties. The "Annual Competency Tool for Nurses, Intrathecal Pump" will be filled out yearly for all Primary Care Nurses, either by their Regional Nurse Manager, or through a peer to peer review, showing that they are competent to perform the necessary procedures and will be kept in their employee files.

Compensation for pool nurses during the classroom period and high stick orientation will be as follows. Please note orientation in the comments section of the expense sheet:

0-4 hours/day = Partial day/\$160

4+hours/day = Full day/\$320

Effective: 10/09
 Revised: 4/10
 Reviewed: 7/10
 Revised: 6/11
 Revised: 9/11
 Revised: 4/12
 Revised: 8/12

SUPPLEMENTAL
#2

PENTEC HEALTH, INC.

SUPPLEMENT NO. 2

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

DECEMBER 2014

December 10, 2014**10:13 am****1. Section A, Item 4**

Review of the Annual Report of Pentec Health, Inc. filed 1/2012 with the TN Secretary of State's Office (page 99 of revised application) identified the names of the parent company's Board of Directors. What are the qualifications of the members as it relates to the responsibilities of the Board for oversight of the proposed home health organization? What changes to the responsibilities of the Board will be made to incorporate oversight responsibilities for operations of the proposed HHA to be added to the Board's responsibilities for Pentec Health's existing pharmacy operations in Tennessee.

The information on file with the Tennessee Secretary of State is not completely up to date, as several Directors of Pentec Health, Inc. have changed. A current list of Directors follows:

Name	Position/Title	Occupation	Employer	Business Address
Joseph Cosgrove	Director; President/CEO; Secretary; Treasurer	Healthcare Executive	Pentec Health, Inc.	4 Creek Parkway Boothwyn, PA 19061
Brian Morfitt	Director	Private Equity Executive	Frazier Healthcare Partners	601 Union Square Suite 3200 Seattle, WA 98101
Andrew Carragher	Director	Private Equity Executive	DW Healthcare Partners	1413 Center Drive Suite 220 Park City, UT 84098
Rod Boone	Director	Private Equity Executive	DW Healthcare Partners	1413 Center Drive Suite 220 Park City, UT 84098
Tim Kuehl	Director	Private Equity Executive	Norwest Equity Partners	80 South 8th Street Suite 3600 Minneapolis, MN 55402
John Lindahl	Director	Private Equity Executive	Norwest Equity Partners	80 South 8th Street Suite 3600 Minneapolis, MN 55402
Carter Balfour	Director	Private Equity Executive	Norwest Mezzanine Partners	80 South 8th Street Suite 3600 Minneapolis, MN 55402

Joseph Cosgrove is the Chairman of the Board of Directors. He has served as President and CEO, Secretary and Treasurer of Pentec since 2008. Mr. Cosgrove has more than 20 years of diversified life sciences industry experience in both the public and private sectors. Prior to joining Pentec, he served as Vice President and General Manager for several operating units of Cardinal Health Inc., including Nuclear Pharmacy Services from 2002 to 2006, and Global Pharmaceutical Services from 2006 to 2008. Prior to Cardinal Health, Mr. Cosgrove worked for DuPont Pharmaceuticals Company as Senior Director of sales, marketing and strategic planning, and Senior Director of national accounts.

The other Directors represent Pentec's principal shareholders. Brian Morfitt is a General Partner of Frazier Healthcare Partners, a private equity firm that invests exclusively in healthcare companies. In addition to Pentec's Board, Mr. Morfitt serves on the boards of TridentUSA Health Services, Correct Care Solutions, Informed Medical Communications and Orthotic Holdings Inc. Andrew Carragher is the founder and Managing Director of DW

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Healthcare Partners, a private equity firm that invests solely in healthcare companies. In addition to serving as a Pentec Director, Mr. Carragher is a director of Genesis Technology Partners, Verathon, Tandem Labs, Reliant Renal Care, Reliant Rehabilitation, Career Step, Z-Medica Corporation, Health & Safety Institute, ABC Home Medical Supply and Aerosol Science Laboratories Inc. Rod Boone is a Managing Director of DW Healthcare Partners, and has over 20 years of experience building and operating healthcare companies. In addition to Pentec's Board, Mr. Boone serves on the boards of ABC Home Medical Supply, Aerosol Science Laboratories Inc., Career Step, Emphusion, Health & Safety Institute, Hill Top Research and Tandem Labs, Inc. John Lindahl is the founder and Chairman of Norwest Equity Partners, a private equity firm, and is an investment and financial professional with more than 40 years of experience. Tim Kuehl is a Partner at Norwest Equity Partners, and is a financial and investment professional. Carter Balfour is a Partner at Norwest Mezzanine Partners, and is also a financial and investment professional.

The Board of Directors of Pentec has all of the responsibilities of a board of directors of a Pennsylvania business corporation as provided in the Pennsylvania Business Corporation Law of 1988. As such, the Board is responsible for oversight of all aspects of Pentec's operations, including its Specialty Infusion and Renal Nutrition divisions, and its closed-door pharmacy, which supports both of the foregoing divisions. Therefore, the Board is already responsible for oversight of Pentec's home health care operations and its pharmacy operations in all states in which Pentec is active. The only change to the Board's area of responsibility would be the addition of Tennessee to the jurisdictions for which it oversees home health care operations.

Specific Board responsibilities for oversight of home health care operations include, but are not limited to, the following:

- Appointment of the HHA administrator
- Adoption and approval of comprehensive policies and procedures for the HHA
- Adoption and approval of quality assurance and performance improvement policies and programs and review of program results
- Appointment of an advisory board for the HHA, when required by applicable law
- Ongoing review of HHA operations, including financial performance

December 10, 2014**10:13 am****2. Section A, Applicant Profile, Item 13**

It appears that the certification status of the existing pharmacy (limited to renal nutrition services) is provided in this item and will not apply to the proposed HHA. HSDA staff is under the impression that the applicant does not plan to seek Medicare/Medicaid certification for the proposed home health agency. In addition, it appears that the applicant may provide services to enrollees of these programs on a limited basis and only under the terms of the Compassionate Care policy noted in the response. Is this a fair summary of the applicant's plans in this regard? Please explain.

Although Pentec's pharmacy presently supplies renal nutrition products for use by Tennessee residents, its state certification is not limited to renal nutrition. As stated in Pentec's most recent pharmacy license renewal application, submitted to the Tennessee Board of Pharmacy in March 2014, the pharmacy supplies IV, Intrathecal, TPN, Parenteral and Intraperitoneal compounded products. As such, the pharmacy would supply compounded products for administration to patients of the proposed HHA. As stated correctly above, Pentec would not seek Medicare/Medicaid certification for home health care. Nevertheless, and also as stated above, it would provide services to enrollees of these programs on a limited basis, under its Compassionate Care Policy, No Insurance Policy, or Financial Assistance Policy, as applicable.

In your response, please also describe what arrangements will be made to lift the existing pharmacy restriction (limited to renal nutrition services) and expand to specialty infusion services support for the proposed HHA.

As noted immediately above, Pentec's pharmacy is not restricted or limited to the provision of renal nutrition products. Under its current non-resident Tennessee pharmacy license (No. 4108; valid until March 31, 2016), Pentec may supply compounded medication for administration to patients of the proposed HHA. No further action is required.

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In a recent application, Coram Specialty Infusion services, CN1406-017, the applicant provided a service area study that included a comparison of a typical Medicare-certified home health agency patient to an infusion therapy patient. The comparison was illustrated in the table below from the HSDA staff summary for the project.

Variable	Medicare Home Health Agency	Infusion Nursing Agency	Pentec – Intrathecal Pump Services
Average Visit Duration	One to two hours	Up to six hours	Typically, one to two hours
Equipment	Generally not involved	Typically includes infusion equipment	Administration kit (syringes and other disposable items); pump programmer
Payor	87% Medicare and TennCare patients	Private Insurance mainly	Mostly private insurance
Age	Approximately 73% over age 65	Predominantly under age 65	Approximately 71% under age 65
Service Provided	46% is skilled nursing. Balance of service includes therapy, home health aide, and medical social services.	100% specialized skilled nursing	100% specialized skilled nursing
Patient Status	Homebound	Patient may or may not be homebound	Patient may or may not be homebound

What observations or suggestions can the applicant provide by contrasting its IP intrathecal infusion services program with the categories in the table above? Please feel free to revise the table as appropriate to illustrate the comparison.

The services to intrathecal pump patients that Pentec provides are different from those provided by the traditional, full-service home health agency or by agencies that provide primarily other types of infusion services such as IV infusion. Pentec has the following observations, which are summarized in the right-hand column above.

- The typical visit to an intrathecal pump patient lasts only 1-2 hours (vs. up to 6 hours, e.g., in the case of an Ig-G replacement therapy patient). Although the duration of visits to intrathecal pump patients is comparable to the traditional HHA visit, visits to intrathecal pump patients occur much less frequently than traditional HHA visits – usually one time every 30-60 days.
- In contrast to IV infusion, intrathecal pump refills do not require an infusion pump or other durable infusion equipment. The refill itself requires only a low-cost administration kit consisting of disposable items. If the pump also requires reprogramming, then the nurse will use an external programming device to reprogram the pump.
- As with IV infusion, reimbursement is typically through private insurance plans. This is because the skilled nursing services provided to intrathecal pump patients and the per diem charge typically are not covered under traditional Medicare and Medicaid coverage guidelines.

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- Also like the IV infusion patient population, the overwhelming majority of Pentec's intrathecal pump patients (71%) are under the age of 65. This contrasts sharply with the predominantly geriatric population served by the traditional HHA.
- As with IV infusion, the services provided to intrathecal pump patients consist entirely of skilled nursing (which itself requires completion of a highly specialized training regimen to be performed proficiently). Pentec's proposed HHA would not provide any of the other services offered by traditional HHAs.
- Finally, as with IV infusion patients but unlike the traditional HHA patient, the intrathecal pump patient is not necessarily homebound. In fact, in many cases, intrathecal pump therapy allows patients who might otherwise be homebound or suffer from limited mobility to resume many normal activities including ambulation.

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Item 4.A – Process planned for compounding/preparation, shipping, delivery and safeguard of medications. It appears that the shipping process involves shipping in advance to a Pentec nurse and, in some cases, shipment direct to the patient at his/her home. Please address what flexibility the applicant may have, if any, in changing the model to a 100% patient delivery mode as it pertains to compliance with federal and state requirements.

For a variety of reasons, including minimization of the risk of diversion or abuse of controlled substances, minimization of the risk of loss, and maintenance of proper storage conditions, Pentec's model entails shipment by its pharmacy, pursuant to the order of the prescribing physician, of intrathecal medications to the appropriate primary care nurse. It should be noted that Pentec Health, Inc. is the pharmacy license holder in all 50 states and the District of Columbia; the federal Drug Enforcement Agency ("DEA") registrant (No. BP9684627); and the license holder in those jurisdictions in which a home health or similar agency license is required. Therefore, shipment of intrathecal medications to the primary care nurse in advance of administration to the patient constitutes shipment by the pharmacy to an employee. Pentec notes that the DEA defines "employees" as persons "who are directly paid by the registrant; who are subject to direct oversight by the registrant; who are required, as a condition of employment, to follow the registrant's procedures and guidelines pertaining to the handling of controlled substances; who receive a performance rating or performance evaluation on a regular/routine basis from the registrant; [and] who are subject to disciplinary action by the registrant". 79 Fed. Reg. 53,527 (Sept. 9, 2014). All of the foregoing factors apply directly to Pentec's nurses.

Pentec further notes that its pharmacy shipped approx. 63,000 packages in 2013, and approx. 68,000 packages between January 1 and October 31, 2014, in each case with a 99.99% accuracy rate. Pentec strongly believes that its proven model for handling intrathecal medication is superior to any alternative, and provides the best protection against diversion, abuse, loss and spoilage.

The process appears to apply only to refills and not the initial dosage administration following implant by a physician in a hospital or other appropriate health care facility. Please confirm.

The physician always does the initial dosage administration. If a patient needs to have an intrathecal pump or catheter replaced, the physician usually also does the initial dosage administration immediately after that surgery is completed. Further, the patient typically needs a follow-up appointment with the physician for clearance to have a Pentec nurse administer new medication or perform a refill following such surgery. Thereafter, the process for compounding/preparation, shipping, delivery and safeguard of medications would apply.

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Item 4.C – Examples of patient services. Please also provide examples of the types of clinical classifications that apply to patents served by the proposed HHA such as patients with multiple sclerosis, chronic cancer pain, etc. If possible, please identify diagnostic related group (DRG) codes or the equivalent for IP intrathecal infusion services (note: these would be used by HSDA staff to seek assistance from the Department of Health in identifying the incidence of IP procedures in TN hospitals using data from the Hospital Discharge Data Base).

Typical diagnoses for intrathecal pump patients include:

1. Chronic Pain Syndrome
2. Complex Regional Pain Syndrome
3. Multiple Sclerosis
4. Traumatic Brain Injury
5. Cerebral Palsy
6. Abnormal Involuntary Movement (Spasticity)

Applicable ICD-9-CM diagnosis codes for intrathecal pump patients include the following:

Chronic Pain Disorders

- 338.0 Central pain syndrome
- 338.29 Other chronic pain
- 338.3 Neoplasm-related pain (cancer pain)
- 338.4 Chronic pain syndrome

Reflex Sympathetic Dystrophy and Causalgia

- 337.22 Reflex sympathetic dystrophy of the lower limb (complex regional pain syndrome type I of lower limb)
- 355.71 Causalgia of the lower limb (complex regional pain syndrome type II of lower limb)

Spasticity of Spinal Origin: Multiple Sclerosis

- 340 Multiple sclerosis

Spasticity of Cerebral Origin: Cerebral Palsy

- 343.0 Infantile cerebral palsy, diplegic (congenital diplegia, congenital paraplegia)
- 343.1 Infantile cerebral palsy, hemiplegic (congenital hemiplegia)
- 343.2 Infantile cerebral palsy, quadriplegic (tetraplegic)
- 343.3 Infantile cerebral palsy, monoplegic
- 343.4 Infantile cerebral palsy, infantile hemiplegia (postnatal)
- 343.8 Other specified infantile cerebral palsy
- 343.9 Infantile cerebral palsy, unspecified
- 344.89 Spastic cerebral palsy, not congenital or infantile

Other Spasticity of Spinal or Cerebral Origin

- 342.1X Spastic hemiplegia
- 344.0X Spastic quadriplegia
- 344.1 Spastic paraplegia, non-infantile or congenital
- 344.2 Spastic diplegia of upper limbs
- 344.3X Spastic monoplegia of lower limb
- 344.4X Spastic monoplegia of upper limb

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- 344.5 Spastic monoplegia, unspecified
344.9 Spastic paralysis, unspecified

Intrathecal Injection

- 03.91 Injection of anesthetic into spinal canal for analgesia
03.92 Injection of other agent into spinal canal

Typical diagnoses for Ig-G replacement therapy patients include:

1. Primary Immune Deficiency
2. Auto Immune Disorder

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Item 4.E – Collaboration with existing HHAs and state professional HHA association(s) to identify and assess the need for its specialty IP and Ig-G services. Input from the TN Association of Home Care and the TN Hospital Association is important to a better understanding of the proposed HHA, especially in light of recent HSDA approval of Coram Specialty Infusion Services, CN1406-017A (includes provision of Ig-G replacement therapy services) and a pending application from Implanted Pump Management, Inc. of Wayne, N.J., that is presently being reviewed by the Department of Health for the establishment of a home health organization limited to implanted pump intrathecal infusion therapy (IP) services serving all 95 counties of Tennessee (CN1407-017). In light of these recent developments, support for the applicant's proposed project from these parties may be helpful to HSDA and TDH in the review of the application. Please contact these parties for information related to the need for an additional HHA offering IP and Ig-G services in TN at this time.

Pentec's National Sales Director for Specialty Infusion, Doug Wynd, has contacted the Tennessee Association of Home Care regarding whether intrathecal pump management services are available from licensed home health agencies in Tennessee. The Association advised Mr. Wynd that it is not aware of any licensed Tennessee HHA that provides these services. There are a number of licensed agencies that provide other types of home infusion services, including Ig-G replacement therapy, but they do not provide intrathecal pump management services.

Pentec is aware of the Tennessee CON application submitted by Intrathecal Pump Management, LLC ("IPM"). Pentec is also aware, from testimony provided by IPM's Director of Nursing at an administrative hearing conducted by the Kentucky Cabinet for Health and Family Services on October 15, 2014, that IPM's parent, Basic Home Infusion, Inc. ("BHI"), presently serves intrathecal pump patients in Tennessee by independently contracting with a nurse licensed to practice in Tennessee to perform the services. (Transcript of testimony of Melissa Hill, R.N., In re: Implanted Pump Management, LLC, CON #000-00-5591(1), Oct. 15, 2014, volume I, pages 39-40.) Pentec believes that its model of patient care, involving the use of registered nurses who are Pentec employees, who have completed Pentec's comprehensive, ANCC-accredited primary care nurse training program, and who are subject to ongoing performance and competency evaluation, is superior, particularly in light of the risks inherent in intrathecal pump therapy.

What source(s) of information did the applicant have at its disposal in identifying the 2 organizations as current or possible providers of IP intrathecal in-home services? Is the applicant aware of their IP intrathecal infusion utilization for the most recent 12 month period available? Please clarify. (Note: applies to names provided - Professional Home Health (license # 96030) and Basic Home Infusion (not an existing licensed HHA in Tennessee)).

Pentec had contact with Professional Home Health in connection with Pentec's application for a Certificate of Need for a mobile health service in Kentucky, and is aware from those contacts that Professional is active in Tennessee as well as Kentucky. Pentec cannot provide information regarding Professional's intrathecal services utilization. The 2013 Joint Annual Report does not include specific data regarding intrathecal services provided. However, the 2013 Joint Annual Report does indicate that for the agency as a whole, 20.0% of total reported nursing visits were "skilled nursing care" visits, and intrathecal pump services would fall into this category. Of the agency's 2,641 reported patients, 13 were from

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2 counties in Tennessee. Even if all of these were intrathecal pump patients, the data indicate that the service provided by Professional in Tennessee is very limited.

Pentec has been aware for many years of BHI's operations in many jurisdictions. As noted above, Pentec is also aware of the application by BHI's wholly-owned subsidiary, IPM, for a Certificate of Need to establish a limited HHA in Tennessee and of BHI's present operations in Tennessee conducted through the use of an independent contractor nurse.

Item 4.F – Patient services provided by staff RNs. Are there instances where RN staff might be present with physicians and their patients for initial IP medication administration? Please briefly describe.

The initial administration of medication is done by the treating physician immediately after surgical implantation of the intrathecal pump. During the entire surgery, a pump representative from the pump manufacturer is present to assist the surgeon as needed. A Pentec primary care nurse is not present. On rare occasions, a patient does not receive the initial dose immediately after the surgery and saline is instilled in lieu of medication. In those instances, the patient instead receives the initial dose administration in the physician's office at a follow-up visit. Pentec's nurse may be present during that follow-up visit, but does not assist with or perform the procedure unless the guidelines set forth in Pentec's post-surgical policies have been met.

Please also briefly describe the process that will be followed to ensure cross checking when pumps need to be reprogrammed for changes in medication dosage.

Pentec's process includes the following:

1. Following Pentec's Safety Checklist: reviewing pump telemetry with the patient and/or caregiver immediately following programming of the pump of any kind.
2. Uploading pump telemetry on the day of the visit.
3. Using demo mode prior to complex programming and prior to patient visit.
4. Reviewing demo mode telemetry prior to, and telemetry reviewed after, patient visit with a Pentec Regional Nurse Manager or nurse trainer to verify accuracy of any complex programming.

Copies of Pentec's "Patient Safety Checklist" Policy and the "Patient Safety Checklist" used by its primary care nurses are attached to this Supplement as Attachment to Question 3, Item 4.F.

4. **Section C, Need, Item 1.a. (Project Specific Criteria-Home Health Services, Items 1 through 4)**

Alecia Craighead, Statistical Analyst, HSDA staff, reviewed the response and noted a few minor changes to Exhibit 1. Please revise Exhibit 1 with the entries included in the table below.

Existing Licensed HHAS & Their Utilization serving the 95 County Declared Service Area

Agency Name (license #)*	County of Parent Office	Total Counties authorized in license (# counties in service area) **	2010 JAR Total patients served	2011 JAR Total patients served	2012 JAR Total patients served
Amedisys Home Health	Davidson	22 (22)	1,538	1,598	2,008
CareAll Homecare Services	Davidson (formerly in Wilson County)	21 (21)	1,473	1,292	1,562

The revised Exhibit 1, reflecting the foregoing changes, is set forth below:

Exhibit 1

Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Accredo Health Group, Inc.	79456	Shelby	6 (6)	9	14	20
Advanced Home Care, Inc.	82051	Sullivan	8 (8)	2825	2583	2245
Advanced Home Care, Inc.	30021	Greene	4 (4)	385	526	762
Alere Women's and Children's Health, LLC	33423	Hamilton	13 (13)	18	52	74
Alere Women's and Children's Health	79466	Shelby	7 (7)	357	401	417
Alere Women's and Children's Health, LLC	19654	Davidson	14 (14)	140	196	202
Amedisys Home Health	67024	Overton	11 (11)	1325	1277	1453
Amedisys Home Care	26054	Franklin	15 (15)	1015	1074	1150
Amedisys Home Care	79146	Shelby	3 (3)	882	938	1060
Amedisys Home Health	19674	Davidson	22 (22)	1538	1598	2008
Amedisys Home Health	90121	Washington	6 (6)	2496	2384	1821
Amedisys Home Health	33103	Hamilton	19 (19)	3358	3342	2878
Amedisys Home Health	79386	Shelby	4 (4)	2411	1806	1934
Amedisys Home Health	75054	Rutherford	7 (7)	543	554	661
Amedisys Home Health Care	47202	Knox	27 (27)	5267	5420	5354
Amedisys Home Health Care	57075	Madison	19 (19)	2489	2586	2741

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Amedisys Home Health Care	10031	Carter	7 (7)	1241	1147	1171
Amedisys Home Health Care	75064	Rutherford	17 (17)	1476	1431	1582
Amedisys Home Health Care	32102	Hamblen	13 (13)	3613	3675	3896
Amedisys Home Health Care	79246	Shelby	3 (3)	576	683	936
Amedisys Home Health of Tennessee	13022	Claiborne	5 (5)	1730	2074	1830
Amedisys Home Health Svcs.	19684	Davidson	10 (10)	756	388	23
Americare Home Health Agency, Inc.	79256	Shelby	2 (2)	1324	1727	1811
Baptist Home Care and Hospice - Covington	84046	Tipton	5 (5)	326	361	353
Baptist Memorial Home Care	09065	Carroll	11 (11)	235	213	262
Baptist Trinity Home Care	79276	Shelby	3 (3)	3248	3367	3862
Baptist Trinity Home Care - Private Pay Division	79446	Shelby	1 (1)	1	1	1
Best Nurses, Inc.	79546	Shelby	3 (3)	311	366	364
Blount Memorial Hospital Home Health Services	05012	Blount	19 (19)	1357	1308	1224
C.M.C. Home C.A.R.E.	18054	Cumberland	1 (1)	536	409	407
Camellia Home Health of East Tennessee, LLC	47062	Knox	22 (22)	1448	1556	1716
CareAll Homecare Services	19724	Davidson (formerly Wilson)	21 (21)	1473	1292	1562
Careall Home Care Services	89074	Warren	8 (8)	520	337	637
CareAll Home Care Services	47232	Knox	6 (6)	257	278	510
CareAll Homecare Services	84076	Tipton	14 (14)	1491	1103	1556
CareAll Home Care Services	92025	Weakley	12 (12)	1903	2668	2036
CareAll Homecare Services	60074	Maury	11 (11)	285	224	609
Caresouth HHA Holdings of Winchester, LLC	26024	Franklin	35 (35)	1395	1371	2030
Suncrest Home Health	13032	Claiborne	11 (11)	436	581	852
Clinch River Home Heath	01032	Anderson	7 (7)	473	468	461
Continucare Healthservices, Inc. - I	33213	Hamilton	8 (8)	1638	1494	1466
Continucare Healthservices, Inc. - II	33383	Hamilton	11 (11)	21	17	8
Continuous Care Services, LLC	19664	Davidson	6 (6)	905	671	407
Coram Specialty Infusion Services	19734	Davidson	37 (37)	-	-	11
Covenant Homecare	47402	Knox	16 (16)	3838	3946	3953
Cumberland River Homecare	14024	Clay	10 (10)	361	236	392
Deaconess Homecare II	36025	Hardin	11 (11)	1213	1244	1330
Deaconess Homecare	76032	Scott	5 (5)	406	352	394
Deaconess Homecare	52024	Lincoln	24 (24)	712	704	842
Deaconess Homecare	95034	Wilson	21 (21)	1237	1210	1222
East Tennessee Children's	47222	Knox	16 (16)	671	559	586

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Hospital Home Health Care						
Extended Health Care, Inc.	79136	Shelby	6 (6)	780	341	79
Elk Valley Health Services, LLC	19494	Davidson	95 (95)	250	245	277
Lifeline of West Tenn., LLC	57095	Madison	20 (20)	962	993	1085
Extendicare Home Health Care of Union City, LLC	66035	Obion	5 (5)	398	347	302
Family Home Care, Cleveland	06043	Bradley	5 (5)	673	1023	598
Family Home Health Agency	79206	Shelby	1 (1)	375	863	379
Friendship Home Health, Inc.	89084	Warren	10 (10)	1025	1345	1724
Friendship Home Healthcare, Inc.	19614	Davidson	14 (14)	1040	1093	845
Angel Private Duty and Home Health, Inc.	19714	Davidson	24 (24)	10	73	123
Functional Independence Home Care, Inc.	79496	Shelby	3 (3)	729	804	953
Gateway Home Health, Clarksville	63034	Montgomery	7 (7)	1050	1067	949
Gentiva Health Services	19084	Davidson	12 (12)	1239	1239	1003
Gentiva Health Services	47042	Knox	16 (16)	898	870	779
Gentiva Health Services	16024	Coffee	9 (9)	726	629	424
Gentiva Health Services	33093	Hamilton	12 (12)	487	268	328
Gentiva Health Services	82061	Sullivan	9 (9)	1286	979	936
Gentiva Health Services	95074	Wilson	15 (15)	1705	1482	1380
The Home Option by Harden Health Care	47372	Knox	8 (8)	0	1	29
Girling Health Care, Inc.	47182	Knox	18 (18)	1093	1031	1467
Guardian Home Care of Nashville, LLC	94074	Williamson	15 (15)	1265	1365	1370
Guardian Home Care, LLC	33083	Hamilton	9 (9)	2179	2116	1484
Hancock County Home Health Agency	34011	Hancock	4 (4)	297	323	463
Henry County Medical Center Home Health	40075	Henry	5 (5)	355	399	363
Heritage Home Health	02024	Bedford	6 (6)	282	280	241
Hickman Community Home Care, Inc.	41034	Hickman	7 (7)	146	134	214
Highland Rim Home Health Agency	71014	Putnam	7 (7)	555	495	574
HMC Home Health, LLC	36035	Hardin	5 (5)	252	274	341
Home Care of Chattanooga	33133	Hamilton	3 (3)	208	119	269
Home Health Care of East Tennessee, Inc.	06063	Bradley	17 (17)	4764	4755	3318
Home Health Care of Middle Tennessee, LLC	19584	Davidson	14 (14)	4246	3914	2963
Home Health Care of West Tennessee, Inc.	79486	Shelby	4 (4)	1308	1118	1010
Health at Home	94094	Williamson	1 (1)	63	50	58
Homechoice Health Services	79376	Shelby	6 (6)	2887	1788	861
Hometown Home Health Care, Inc.	37021	Hawkins	3 (3)	173	-	89

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Innovative Senior Care Home Health	19504	Davidson	22 (22)	73	504	677
Interim Healthcare of Memphis, Inc.	79056	Shelby	3 (3)	720	889	769
Intrepid USA Healthcare Services	62052	Monroe	15 (15)	238	259	358
Intrepid USA Healthcare Services	71084	Putnam	8 (8)	244	341	327
Intrepid USA Healthcare Services	79226	Shelby	4 (4)	662	615	605
Intrepid USA Healthcare Services	57165	Madison	15 (15)	294	86	422
Intrepid USA Healthcare Services	19364	Davidson	11 (11)	644	920	766
Intrepid USA Healthcare Services	89064	Warren	11 (11)	650	159	822
Johnson County Home Health	46031	Johnson	3 (3)	403	396	446
Laughlin Home Health Agency	30041	Greene	5 (5)	553	547	655
Home Care Solutions	19544	Davidson	46 (46)	2192	2080	1930
Home Care Solutions	33363	Hamilton	10 (10)	727	734	663
Life Care at Home of Tennessee	33303	Hamilton	10 (10)	616	989	956
Lifeline Home Health Care	74064	Robertson	5 (5)	289	336	428
Lincoln Medical Home Health and Hospice	52044	Lincoln	7 (7)	356	396	348
Magnolia Regional Health Center Home Health and Hospice Agency	96010	Unknown	2 (2)	1000	915	856
Maury Regional Home Services	60044	Maury	8 (8)	1188	1220	1151
Maxim Healthcare Services	33433	Hamilton	8 (8)	71	150	56
Maxim Healthcare Services, Inc.	47432	Knox	18 (18)	159	150	159
Maxim Healthcare Services, Inc.	79536	Shelby	6 (6)	103	197	155
Maxim Healthcare Services, Inc.	19704	Davidson	9 (9)	138	141	106
Medical Center Home Health, LLC	57055	Madison	14 (14)	1403	1617	1706
Medical Center Homecare Services	90091	Washington	5 (5)	2801	3118	3503
Medical Center Homecare, Kingsport	90081	Washington	7 (7)	1126	1628	1960
Memorial Hospital Home Health	33253	Hamilton	10 (10)	3469	3264	2439
Tennove Home Health	47092	Knox	14 (14)	3586	3188	3063
Methodist Alliance Home Care	79316	Shelby	3 (3)	3226	3180	3179
University of TN Medical Center Home Health Services	32122	Hamblen	10 (10)	986	1244	1327
NHC Homecare	60024	Maury	22 (22)	2212	2134	2408
NHC Homecare	27025	Gibson	12 (12)	479	625	569
NHC Homecare	54043	McMinn	8 (8)	221	183	239
NHC Homecare	24026	Fayette	8 (8)	254	217	226
NHC Homecare	75024	Rutherford	24 (24)	3007	3269	3776
NHC Homecare	90131	Washington	7 (7)	241	264	259
NHC Homecare	47012	Knox	15 (15)	575	567	613
NHC Homecare	33033	Hamilton	10 (10)	199	203	354
NHC Homecare	74054	Robertson	6 (6)	867	909	1332

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
No Place Like Home, Inc.	79506	Shelby	3 (3)	38	55	58
Premier Support Services	32132	Hamblen	16 (16)	972	900	1169
Premiere Home Health, Inc.	19374	Davidson	1 (1)	118	81	87
Procure Home Health Services	30051	Greene	6 (6)	418	384	433
Professional Case Management of Tennessee	01042	Anderson	11 (11)	127	182	164
Professional Home Health Care Agency, Inc.	96030	Unknown	2 (2)	3021	2985	2641
American National Home Health	95084	Wilson	9 (9)	217	358	311
Quality First Home Care	60084	Maurry	5 (5)	906	855	923
Quality Home Health	25044	Fentress	13 (13)	4540	4012	3404
Quality Private Duty Care	25034	Fentress	9 (9)	599	703	879
Regional Home Care Parkway	96020	Unknown	1 (1)	31	14	28
Regional Home Care, Jackson	57085	Madison	15 (15)	1206	1061	1164
Regional Home Care, Lexington	39035	Henderson	22 (22)	578	616	569
Regional Home Care, Dyersburg	23035	Dyer	6 (6)	744	814	707
Senior Services Home Health	79106	Shelby	1 (1)	642	697	609
Smoky Mountain Home Health and Hospice, Inc.	15032	Cocke	12 (12)	1622	1535	1296
Still Waters Home Health Agency	79526	Shelby	1 (1)	105	127	101
Highpoint Homecare	80064	Smith	8 (8)	312	280	377
Highpoint Homecare	83114	Sumner	6 (6)	978	738	855
Sunbelt Homecare	07032	Campbell	7 (7)	285	260	261
SunCrest Home Health	21024	DeKalb	7 (7)	1406	1501	1568
SunCrest Home Health	19324	Davidson	12 (12)	5428	6710	5490
SunCrest Home Health of Manchester, Inc.	16034	Coffee	15 (15)	988	1114	1588
SunCrest Home Health of Nashville, Inc.	63044	Montgomery	6 (6)	229	381	587
Sweetwater Hospital Home Health	62062	Monroe	5 (5)	462	569	613
Tennessee Quality Homecare – Northwest	03025	Benton	15 (15)	1129	1128	1164
Tennessee Quality Homecare - Southwest	20045	Decatur	15 (15)	1352	1082	1080
Unicoi County Home Health	86051	Unicoi	1 (1)	246	209	206
University of TN Medical Center Home Care Services - Home Health	47132	Knox	15 (15)	2530	3264	3439
Vanderbilt Community and Home Services	19394	Davidson	7 (7)	1179	1230	1879
Vanderbilt Home Care Services	19314	Davidson	7 (7)	1180	1268	1812
Volunteer Home Care, Inc.	27085	Gibson	13 (13)	2549	3027	3041
Volunteer Homecare of West Tennessee, Inc.	20055	Decatur	13 (13)	1598	1503	1534
Vanderbilt HC Affiliated Walgreens IV and RT Services	94084	Williamson	33 (33)	81	86	67

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Agency Name	License #*	County of Parent Office	Total Counties authorized in license (# counties in service area)**	2011 JAR Total patients served	2012 JAR Total patients served	2013 JAR Total patients served
Where The Heart Is, Inc.	24036	Fayette	3 (3)	253	271	116
Willowbrook Home Health Care Agency, Inc.	19694	Davidson	36 (36)	3088	2149	1565
Willowbrook Visiting Nurse Association, Inc.	79236	Shelby	6 (6)	473	533	479
Woods Home Health, LLC	54083	McMinn	4 (4)	297	349	283

** Please highlight any HHA in bold font that offers intrathecal home infusion services, even if on a limited basis.*

*** Please show the # of all counties for each HHA. The # of counties in the applicant's service area should be shown separately in the bracket.*

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5. Section C. Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

The applicant notes that letters of support will be provided in a future supplemental response. In addition to letters from physicians, written support from other referral sources such as hospitals and HHAs, and patients would be helpful. Please note the following:

A. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

Pentec's regional manager for Specialty Infusion with responsibility for Tennessee has called on physicians and other referral sources throughout Tennessee and continues to do so. Pentec has received one letter of support, from Comprehensive Pain Specialists of Hendersonville, Tennessee (Richard Muench, M.D.), which is attached to this Supplement as Attachment to Question 5, Item A. Pentec will provide additional letters of support as a further supplement to its CON application as soon as they are available.

B. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

Please see the answer to Question 5, Item A, above.

December 10, 2014**10:13 am****6. Section C. Need, Item 1 (Specific Criteria: Items 6a and 6b)**

Based on the response, it appears that the average billed cost per visit would amount to approximately \$2,513 per visit in lieu of \$2,471 per visit noted on page 30 of the revised application. In addition, it appears that the average cost per patient may change to \$15,078 in lieu of \$14,826 per patient noted on page 31. Please clarify.

The higher numbers shown above (\$15,078 average annual cost per patient and \$2,513 average cost per visit) are more accurate. They were calculated as follows: (1) the \$15,078 average annual cost per patient = estimated Year 1 total revenue of \$304,573 divided by 20.2, the average Year 1 patient census; (2) the \$2,513 average per visit cost per patient = the average annual cost per patient of \$15,078 divided by 6, the assumed number of visits. The lower numbers previously reported reflected rounding errors and an approximation of blended revenue for full-pay and partial-pay patients, and should be disregarded.

A better approach may be to provide separate data for full-pay and partial-pay patients for Year 1, as follows:

Full-pay (third-party insurance) – Year 1 average patient census = 10.4167

Cost (\$)	Per diem	Nursing	Drugs	Supplies	Total
Total	218,284	3,455	38,969	776	261,483
Annual per patient	20,955	332	3,741	75	25,102
Per visit	3,493	55	623	12	4,184

Partial-pay (Medicare/Medicaid) – Year 1 average patient census = 9.75

Cost (\$)	Per diem	Nursing	Drugs	Supplies	Total
Total	2,656	3,234	36,474	727	43,090
Annual per patient	272	332	3,741	75	4,419
Per visit	45	55	623	12	737

All patients – Year 1 average patient census = 20.1667

Cost (\$)	Per diem	Nursing	Drugs	Supplies	Total
Total	220,940	6,689	75,423	1,503	304,573
Annual per patient	10,956	332	3,740	75	15,103
Per visit	1,826	55	623	12	2,517

The foregoing projections are based on actual 2013 charges in connection with Specialty Infusion services provided in the other states in Pentec's service area. Pentec is reimbursed for services provided by national and local insurance plans, and it bills in accordance with the insurers' charge schedules. In addition, some state Medicaid plans provide limited reimbursement for nursing and per diem charges, in addition to drugs and supplies, and that is reflected in the estimates above. For these reasons, actual Tennessee results could vary from the projections. However, Pentec believes that the Projected Data Chart (set forth on page 46 of its revised CON application) presents reasonable estimates for Years 1 and 2.

December 10, 2014**10:13 am****7. Section C, Economic Feasibility, Item 4 – Historical and Projected Data Chart and Item 5**

Item 4 – Based on the response provided in Item 13 on page 39 of the 11/25/14 Supplemental Response, the \$304,573.00 revenue entry in line B.2 of the Projected Data Chart appears to pertain to net operating revenue only. If so, the amount would need to be shown as Net Operating Revenue in a revised chart.

There is a difference in the treatment of "Provisions for Bad Debt" between the Projected Data Chart (on page 46 of Pentec's revised CON application) and Pentec's audited financial statements (on page 133 of Pentec's revised CON application). In the Projected Data Chart, "Provisions for Bad Debt" (line item C.3) is shown as a deduction from Gross Operating Revenue and appears above the Net Operating Revenue line. In Pentec's audited financial statements, this item is shown as an Operating Expense, which is below the Net Operating Revenue line. This means that the Gross Operating Revenue line item on the Projected Data Chart is the equivalent of the "Net Patient Services Operating Revenue" line item in Pentec's audited financial statements. Therefore, unless "Provisions for Bad Debt" is shown as "0" and the projected number is moved to Other Expenses (line item D.8), it is appropriate to show total projected Year 1 revenue of \$304,573 in the Gross Operating Revenue line of the Projected Data Chart.

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Are there management fees to affiliates or non-affiliates associated with this project? Are there any Other Expenses in amounts of \$50,000 or more? If so, please enter the information in the templates provided in the exhibit at the end of this questionnaire and submit as a replacement chart for the application (please number the pages 44-R and 46-R, as appropriate).

There are no management fees to either affiliates or non-affiliates associated with the project.

There are Other Expenses in amounts of \$50,000 or more for each of the three historical periods reported in the Historical Data Chart and for Year 2 (2016) in the Projected Data Chart. Per telephone conversation with Mr. Grimm of the Tennessee Health Services and Development Agency on December 3, 2014, historical and projected information regarding the composition of Other Expenses is set forth in the tables below:

HISTORICAL DATA CHART – OTHER EXPENSES

Other Expenses Categories	Year 2011	Year 2012	Year 2013
Sales and Marketing Expense	\$2,605,000	\$3,259,000	\$2,667,000
General And Administrative Expenses	\$2,646,000	\$3,259,000	\$2,934,000
One-time charges	\$1,271,000	\$6,474,000	\$3,111,000
Goodwill Impairment	\$0	\$46,482,000	\$0
Amortization	\$145,000	\$4,909,000	\$8,326,400
Interest Expense (Income)	(\$18,000)	(\$19,000)	(\$24,000)
Gain / Loss on Disposal	\$12,000	\$16,000	\$14,000
Total Other Expenses	\$6,661,000	\$64,380,000	\$17,028,400

PROJECTED DATA CHART – OTHER EXPENSES

Other Expenses Categories	Year 2015	Year 2016
Sales and Marketing Expense	\$18,884	\$52,943
General And Administrative Expenses	\$45,686	\$128,088
One-time charges	\$0	\$0
Goodwill Impairment	\$0	\$0
Amortization	\$0	\$0
Interest Expense (Income)	\$0	\$0
Gain / Loss on Disposal	\$0	\$0
Total Other Expenses	\$64,569	\$181,032

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Item 5 – Based on the applicant's accounting convention of reporting at the net revenue line item, it appears that the information below for Year 1 may apply. Please confirm.

Average gross operating revenue = 0

Average contractual adjustments = 0

Average Net Operating revenue= \$14,098 per patient or \$2,350 per visit

As discussed in the answer to Question 7, Item 4 of this Supplement, the "net revenue line item" reported by Pentec in its audited financial statements, entitled "Net Patient Services Operating Revenue" (please see page 133 of Pentec's CON application), is the equivalent of the "Gross Operating Revenue" line item on the Projected Data Chart due to the difference in treatment of "Provisions for Bad Debt" between the Projected Data Chart and Pentec's audited financial statements.

It is correct to state that average contractual adjustments per patient = \$0 for Year 1. However, as discussed in the answer to Question 6 of this Supplement, Pentec's projected Year 1 total revenue (i.e., Gross Operating Revenue) = \$15,103 per patient and \$2,517 per visit. Total projected Provisions for Bad Debt for Year 1 = \$19,797, as shown in the Projected Data Chart at line item C.3. Based on the average Year 1 patient census of 20,1667, projected Gross Operating Revenue should be reduced as follows:

(\$)	Total	Annual per patient	Per visit
Gross Operating Revenue	304,573	15,103	2,517
Provisions for Bad Debt	(19,797)	(982)	(164)
Net Operating Revenue	284,775	14,121	2,354

December 10, 2014**10:13 am****8. Section C, Economic Feasibility, Item 9**

The completed chart is noted. It appears that Medicare and Medicaid revenue would not be the case absent certification of the proposed HHA. Shouldn't the combined amount incurred by non-covered enrollees of these programs be reported as "Compassionate Care" in the table below (Charity has been removed per the applicant)? If so, please revise the response by using the table below.

Payor	Year One Gross Revenues	As a % of total Gross Revenue
Medicare		
Medicaid/TennCare		
Commercial insurance		
Self-Pay		
Compassionate Care		
Total		

The chart as provided in the answer to Question 16 at page 42 of Supplement No. 1 is correct. This is because Pentec, as a licensed non-resident Tennessee pharmacy that is a Medicare and Medicaid provider, would be able to bill these programs for drugs and supplies, at a minimum. The chart provided in Supplement No. 1 is presented again below for reference.

Payor	Year One Gross Revenues	As a % of total Gross Revenue
Medicare	\$21,545	7%
Medicaid/TennCare	\$21,545	7%
Commercial insurance	\$261,483	86%
Self-Pay	\$0	0%
Charity	Not reported	NA
Total	\$304,573	100%

December 10, 2014**10:13 am****9. Additional information for future review by Tennessee Department of Health**

Following notification by the HSDA Executive Director that initial review of the proposal by HSDA staff is complete, the applicant will undergo a 60-day review period by TDH and possibly the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS). To facilitate their review (at least initially), please provide a response for the questions that are included in Exhibit 2 at the end of this questionnaire.

Answers have been provided in Exhibit 2 of this Supplement.

December 10, 2014**10:13 am****10. Proof of Publication**

Clarification to follow by the applicant in a future supplement is noted as to the status for the 3 counties – Hancock, Perry and Van Buren Counties. Thank you for following up on this item.

An affidavit of publication from the Tennessee Press Service, which is in addition to the proofs of publication already provided, is attached to this Supplement at Attachment to Question 10.

Pentec has contacted the applicable newspapers regarding circulation in Hancock, Perry and Van Buren counties, and is awaiting responses.

December 10, 2014**10:13 am****Exhibit 1 – Historical & Projected Data Charts**

The HSDA is utilizing more detailed Historical and Projected Data Charts. Please complete the revised Projected Data Chart provided at the end of this request for supplemental information. Please note that "Management Fees to Affiliates" should include management fees paid by agreement to the parent company, another subsidiary of the parent company, or a third party with common ownership as the applicant entity. "Management Fees to Non-Affiliates" should also include any management fees paid by agreement to third party entities not having common ownership with the applicant. Management fees should not include expense allocations for support services, e.g., finance, human resources, information technology, legal, managed care, planning marketing, quality assurance, etc. that have been consolidated/centralized for the subsidiaries of a parent company.

As noted in the answer to Question 7 of this Supplement, there are no management fees to either affiliates or non-affiliates associated with the project.

Also as noted in the answer to Question 7 of this Supplement, per telephone conversation with Mr. Grimm of the Tennessee Health Services and Development Agency on December 3, 2014, historical and projected information regarding the composition of Other Expenses is presented in the answer to Question 7, rather than in revised Historical and Projected Data Charts.

EXHIBIT 2 – Reviewing Agency Questions**Issue: Administration of Home Service – Licensure Requirements**

1. **To the best knowledge of TDH, intrathecal medication administration is not generally taught in nursing school. Is any certification required or available for performing IP services?**

State certification is not available, but Pentec has developed a comprehensive program of classroom and field training for its primary care nurses is accredited through the American Nurses Credentialing Center ("ANCC"). Pentec believes that its nurse training program is unique, and stands in sharp contrast to the limited nurse training provided by many other agencies offering intrathecal pump services (e.g., reliance on training provided by pump manufacturers).

Pentec's nurse training program is discussed in its revised CON application at Section C, Contribution to the Orderly Development of Health Care, Item 5, under the heading "Staff Education" (pages 62-63), and in the answer to Question 5, Item B at page 18 of Supplement No. 1. In addition, a copy of Pentec's Nurse Training Program Policy and Procedure is attached at pages 60-62 of Supplement No. 1 as Attachment to Question 5.B.

2. **If approved, the CON should be limited to IP management; no other home health services should be permitted.**

In its CON application, Pentec has requested authority to establish a specialized home health agency to provide Ig-G replacement therapy services in addition to intrathecal pump services. However, if it is a necessary condition of approval, Pentec would agree to limit its CON to intrathecal pump services.

Issue: Administration of Home Service – Impact of Existing Regulations**1. What participation by physicians will be involved/required in the overall supervision of patient care in addition to implanting of IPs?**

The initial administration of medication is done by the treating physician immediately after surgical implantation of the intrathecal pump. On rare occasions, a patient does not receive the initial dose immediately after the surgery and saline is instilled in lieu of medication. In those instances, the patient instead receives the initial dose administration in the physician's office at a follow-up visit.

If a patient needs to have an intrathecal pump or catheter replaced, the physician usually also does the initial dosage administration immediately after that surgery is completed. Further, the patient typically needs a follow-up appointment with the physician for clearance to have a Pentec nurse administer new medication or perform a refill following such surgery.

The patient's physician will refer the patient to Pentec for treatment, order the patient's plan of care (developed by the primary care nurse with physician assistance), and prescribe all medication to be provided to the patient. In addition, the physician will review the patient's plan of care at least every 60 days; and the physician will be provided with the nurse's assessment made at the start of care and at the time of each visit thereafter.

The patient's primary care nurse reports to the physician any changes that could change the patient's plan of care and treatment goals, which may result in a modified plan of care. If no change to the plan of care is noted by the primary care nurse, the plan will be maintained as signed and noted during the previous certification period, with renewal submitted for physician signature.

Treating physicians have 24/7 access to patient records and real-time updates following patient visits through use of Pentec's proprietary Physician Portal, located on its website, which provides physicians with secure access to patients' medical information and also allows secure, HIPAA-compliant secure, two-way video-conferencing capability ("eVisit") that allows physicians to observe treatment by Pentec's nurse and communicate with the nurse and the patient during the in-home visit.

Issue: Administration of Home Service – Risks Involved

- 1. There are risks of infection, diversion, overdose, and equipment malfunction/troubleshooting. How can patient issues be resolved before it transitions into an emergent situation? How does a patient or caregiver know if there is an emergent situation? The applicant's small staff and large service area increase risk of harm. Additionally, how are workforce sick days and capacity issues to be handled?**

The risk of infection is addressed by the requirement of strict adherence to Pentec's infection control policies. A copy of Pentec's Infection Control Policy and Procedure is attached to this Supplement as Attachment to Exhibit 2, Issue: Administration of Home Service – Risks Involved.

The risk of diversion is addressed in detail in the answer to Question 4, Item G at page 13 of Supplement No. 1.

To the extent reasonably possible, Pentec's contingency planning allows problems such as missed appointments, overdose, and equipment malfunction to be identified and addressed, or avoided entirely, before they result in an emergent situation.

Missed appointments: Intrathecal pump patients must have their pumps refilled and reprogrammed at regular intervals. Because consequences of a pump running dry are serious and sometimes life-threatening, this cannot be allowed to happen, and Pentec has implemented procedures to ensure that it does not happen. Pentec schedules all patient visits 7 to 10 days prior to the "alarm date" (i.e., the date on which the pump must be refilled). This allows adequate time to reschedule in the event that the patient is unable to keep an appointment, the nurse is taken ill, or similar circumstances. In addition, each Pentec primary care nurse (the nurse assigned to a particular patient) is backed up by one or more other nurses who are available to provide care to the primary care nurse's assigned patient if the need arises. Pentec has a sufficient number of nurses licensed to practice in Tennessee to ensure that full coverage is always available.

Overdose; pump malfunction: All Pentec patients (and/or their representatives, if applicable) are educated on the signs and symptoms of medication withdrawal and overdose and the need to seek medical attention in such an event. In addition, Pentec nurses monitor pump battery life and advise patients in advance of the need to have the batteries replaced. (Intrathecal pumps are implanted surgically and batteries must be replaced in a surgical procedure.) However, a malfunction of an intrathecal pump is not an event that can be addressed by a Pentec contingency plan. As with any medical emergency, a patient with a malfunctioning intrathecal pump will need to seek immediate medical attention.

Pentec's ability to cover a large, statewide service area with a relatively small staff is addressed in detail in the answer to Question 4, Item G at page 12 of Supplement No. 1.

Staff capacity and workforce sick days are discussed in the answer to Question 4, Item G at page 12 of Supplement No. 1, and Question 6 at page 20 of Supplement No. 1.

December 10, 2014**10:13 am****Issue: Administration of Home Service – Workforce Qualifications and Training**

1. **The Board of Nursing Rules require that the RN be licensed and be competent (have the education and training) to perform any anticipated services; the applicant therefore must document how the RN is trained to be competent and how the RN will retain those competencies.**

In addition to having and maintaining in good standing a license to practice professional nursing in Tennessee, each Pentec nurse must complete Pentec's in-house, ANCC-accredited primary care nurse training program. This program, which is the only such program of its kind in the United States, includes both classroom and field training and evaluation, and also includes regular refresher training and competency evaluation. Pentec's nurse training program is described in detail at Exhibit 2, Issue: Administration of Home Service – Licensure Requirement, Question 1 of this Supplement.

2. **It is TDH's understanding that the Joint Commission doesn't require nurses to be certified to perform critical care services in, e.g., a hospital.**

The Joint Commission does not provide certification, but ongoing continuing education provides Pentec's nurses with the means to obtain clinical excellence and competencies.

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Issue: Administration of Home Service – Payment for Service Including Participation in TennCare

- 1. TDH understands that TennCare covers IP services performed in a physician's office, but not in the home setting.**

This is correct. TennCare covers the skilled nursing services required to treat intrathecal pump patients when performed in a physician's office, but not when performed in the patient's place of residence.

- 2. No economic impact to TennCare.**

This is correct. Because Pentec's services would be performed in the patient's place of residence, the nursing and per diem components of Pentec's charges would not be covered. Because Pentec is also a non-resident Tennessee pharmacy that is a Medicare and Medicaid provider, it would be able to bill for drugs and the administration kit (low-cost disposable supplies), but TennCare would be billed for these items whether the services are performed in a physician's office setting or in the patient's place of residence.

Issue: Administration of Home Service – Health Plan Consistency: Access, Economic Efficiency, Quality

- 1. The CON would provide greater access to IP services, however greater access must be balanced by the increased risk to patients.**

Pentec believes that the benefits of treatment of patients in their places of residences outweigh any increased risk, and, in some respects, treatment in the home may actually reduce risk. For example, many patients with intrathecal pumps suffer from limited mobility; for these patients, travel to a physician's office for treatment can be burdensome and increases the risk of a missed appointment and the pump running dry – an emergency that can be life-threatening. Furthermore, Pentec has developed and implemented comprehensive policies and procedures that are designed to minimize risk. The risks to patients with intrathecal pumps and the measures taken by Pentec to minimize them are discussed in the answer to Exhibit 2, Issue: Administration of Home Service – Risks Involved, Question 1 of this Supplement.

- 2. There may be a lower cost to the patient in providing this service in the home setting.**

Pentec believes, and research has indicated, that in-home treatment of intrathecal pump patients has the potential to reduce patient use of inpatient and outpatient services as well as ancillary services such as ambulance transport and EMS. The potential for reduction of costs to the patient and to the healthcare system generally are discussed in the answer to Section C, Need, Question 1, under the heading "Principle 3: Economic Efficiencies" at pages 25-26 of Pentec's revised CON application.

- 3. Quality of Care issues:**

- a. An IP patient already has a provider team in place; why fracture the continuity of care? Based on the existence of a provider team, applicant should explain further the need for the service.**

Pentec notes that the proposed services would not entirely replace physician office visits; instead, they become an extension of the physician's care. Pentec's primary care nurses provide services pursuant to a plan of care ordered by and developed in conjunction with the treating physician, and they are in frequent contact with the physician: plans of care is reviewed at least every 60 days, and physicians receive a report immediately following each visit by a Pentec nurse. Treating physicians have 24/7 access to their patients' medical records through Pentec's electronic medical records system, and 24/7 contact with the assigned primary care nurse.

Providing services to intrathecal pump patients in the home can address and mitigate problems caused patient mobility restrictions, burdensome travel to the physician's office for treatment (especially for patients outside urban areas, where travel times and distances can be great due to the limited number of physicians practicing in the area of intrathecal medicine), and long waiting periods in physician offices when the patient is experiencing pain or episodes of spasticity.

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b. Describe the process for dosage adjustments – coordination between applicant's staff and patients' personal physicians

The dose adjustment typically begins with a patient's request to the assigned primary care nurse. The nurse will send an order to the physician's office after discussion with the physician and/or qualified staff on whether and what dose adjustment is appropriate. Confirmation of the physician's order for the adjustment with the physician's signature will be documented in the patient's chart.

The Pentec primary care nurse can also receive a signed physician's order to perform a dose adjustment. Confirmation of the order will be completed by communication with the physician and/or qualified staff and with the patient and/or the patient's caregiver prior to scheduling the patient for the dose adjustment.

The plan of treatment for each intrathecal pump patient includes the patient's medication profile containing all medications ordered by all physicians. It gives the physicians opportunity for medication reconciliation noting all the medications the patient is receiving.

c. Describe the process for monitoring IP maintenance, including troubleshooting of the intrathecal pump.

Intrathecal pump maintenance involves patient and/or caregiver awareness and education. The nurse's assessment of the patient, performed at each visit, always includes visual inspection of the intrathecal pump and catheter areas for signs and symptoms of fluid accumulation, signs and symptoms of infection, possible signs and symptoms of dislodgement or displacement; and the nurse reports any concerns to the treating physician immediately. The patient's intrathecal pump refill interval is always noted along with the alarm date (the date on which the pump *must* be refilled). The patient is scheduled for a refill visit in advance of the alarm date to ensure that the patient's refill is completed in a timely manner. The nurse will also monitor pump battery life and advise patients in advance of the need to have the batteries replaced (a surgical procedure).

An intrathecal pump malfunction cannot be treated by the Pentec nurse. As with any medical emergency, a patient with a malfunctioning intrathecal pump will need to seek immediate medical attention, and will be directed to the nearest hospital emergency department.

Intrathecal pump maintenance also involves patient and caregiver awareness and education. All Pentec patients (and their representatives or caregivers, if applicable) are educated on the signs and symptoms of medication withdrawal and overdose and the need to seek medical attention in such an event.

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- d. **Since physician review of patient condition is dependent upon report by RN, what are provisions for face-to-face assessment by physicians?**

Provisions for a face-to-face physician assessment will depend on the patient's diagnosis, prognosis, current status and any changes in status, as well as applicable state laws governing minimum required frequency of physician examination of patients. The patient will be instructed to follow up with his or her physician in the event of any changes in the patient's assessment, both objective and subjective, by the Pentec primary care nurse. In addition, the nurse will enter notes into Pentec's electronic medical records system immediately after each visit, and these will be provided to the treating physician for review. Frequency of physician face-to-face assessment of intrathecal pump patients can vary greatly depending on the foregoing factors.

Any changes in the status of a patient possibly related to the intrathecal pump or catheter requires urgent or emergent physician assessment and follow-up. These can include sudden changes in pain and/or spasticity levels, sudden neurological, respiratory, or cardiac changes, any signs or symptoms of an infection, any signs or symptoms of fluid accumulation around the intrathecal pump or catheter areas, and signs or symptoms of dislodgement or displacement of the pump or catheter.

Issue: Administration of Home Service – Other Laws, Regulation or Guidelines that the Service/Facility Would Impact

- 1. TDH draft Chronic Pain Guidelines don't address IP services specifically. Morphine equivalents, however, have specific delivery requirements (see 4.c, below).**

Pentec has reviewed the draft Tennessee Chronic Pain Guidelines and notes that the focus of the Guidelines appears to be on the prescribing and control of orally-administered opioids. As noted above, the Guidelines do not address intrathecal delivery of controlled substances by means of a surgically-implanted intrathecal pump. However, as discussed in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1, Pentec is cognizant of the risks posed by diversion of controlled substances, and in response has developed a protocol for shipping, storage and delivery of all intrathecal medication (including opioids/controlled substances) that is designed to ensure continuous Pentec custody of all medication until the time it is administered to the patient.

- 2. The Professional Boards are not yet in position to provide recommendations.**

Pentec strongly believes that its proven model for handling intrathecal medication (including opioids/controlled substances), which entails delivery by Pentec's pharmacy to a Pentec employee for ultimate delivery and administration to the patient, is superior to available alternatives and provides the best protection against diversion, abuse, loss and spoilage.

- 3. How would existing Home Health Agencies that provide infusion services be impacted?**

The impact of the proposed HHA on existing Tennessee agencies that provide home infusion services would be minimal. This is because the proposed services would be limited almost exclusively to patients with intrathecal pumps (although Pentec would offer Ig-G replacement therapy as an ancillary service).

Effective care of intrathecal pump patients requires both the ability to refill medications, which requires a pharmacy license, and the ability to administer medications, which requires very specialized skilled nursing services. Pentec is already licensed in Tennessee as a non-resident pharmacy. Its pharmacy staff is specially trained in the preparation of intrathecal drugs and required packaging and delivery systems, and the medication compounding occurs in an absolutely clean, controlled environment. Pentec presently employs registered nurses licensed in Tennessee or a compact state who would staff the proposed HHA. The nursing skills necessary to administer a patient's medications and effectively monitor the operation of the delivery system are highly specialized. To ensure that its nurses have and maintain the required skills, Pentec has instituted a rigorous in-house program of classroom instruction, field training and proficiency evaluation. All Pentec nurses must successfully complete this program, which is the only such program certified by the American Nursing Credentialing Center ("ANCC"), and maintain required proficiency on an ongoing basis.

Although there are large providers of infusion therapy services with affiliated pharmacies such as Coram Specialty Infusion, these home infusion agencies typically do not provide

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services to patients with intrathecal pumps. The impact on agencies such as these would be small to non-existent, since they serve different patient populations. Other agencies, such as Professional Home Health, do treat intrathecal pump patients, but on a very limited basis. While the approval of Pentec's proposal could affect agencies that provide intrathecal pump services, no presently-licensed HHA is a specialty provider of intrathecal pump services, so the impact would be most likely be small.

4. TDH Rules do not prohibit physician or pharmacist ownership of the applicant and prescribing. However, there are the following issues:

a. Administering: Inside the physician office, prescribing is a permitted "administration" act.

The proposed HHA would not be owned by a physician or a pharmacist, so the foregoing concern would not apply. The applicant, Pentec Health, Inc., is a Pennsylvania business corporation that would be the holder of the certificate of need and the HHA license, and it is also the holder of a Tennessee non-resident pharmacy license. Under the Pentec model, all prescribing of intrathecal medication would be by the treating physician. Pentec's pharmacy would fill the prescription and deliver the medication to a Pentec employee in Tennessee for ultimate administration to the patient by a Pentec registered nurse.

b. Dispensing: Outside of the physician office, it is a "dispensing" act, which falls under the Pain Clinic Guidelines. Physicians cannot "dispense" opioids.

Again, the proposed HHA would not be owned by a physician or a pharmacist, so the foregoing concern would not apply. As noted above, treating physicians will prescribe intrathecal medications (including controlled substances), Pentec's pharmacy will fill the prescriptions, and a Pentec nurse will administer the prescribed medication to the patient.

c. Delivery: The draft Chronic Pain Guidelines require that morphine equivalents be "delivered" directly to the ultimate user by an "agent" of a pharmacist. Are there other Pharmacy guideline requirements?

Under Pentec's model of care for intrathecal pump patients, all medication, including scheduled controlled substances, are delivered by Pentec's pharmacy to a Pentec employee, i.e., the Pentec primary care nurse. The primary care nurse then performs the administration of the medication to the patient.

Pentec has developed a shipping, storage and delivery protocol that is designed to ensure continuous Pentec custody of all medication until the time it is administered to the patient. This protocol is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

d. Transport:

i. There is a risk of opioid diversion. TDH is waiting on Drug Enforcement Agency input.

As noted immediately above, Pentec has developed a shipping, storage and delivery protocol designed to ensure continuous Pentec custody of all medication until the time of administration to the patient, thereby keeping the risk of diversion to an absolute minimum. This is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

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- ii. **Transport of Medications – Licensure; how will the medications be obtained? By the RN from the pharmacy delivered to the patient, by the RN from the physician's office delivered to the patient, by the patient to pick-up directly from the pharmacy?**

For reasons including minimization of the risk of diversion or abuse of controlled substances, minimization of the risk of loss, and maintenance of proper storage conditions, Pentec's model entails shipment by its pharmacy, pursuant to the order of the prescribing physician, of intrathecal medications to the appropriate primary care nurse. Pentec Health, Inc. is the pharmacy license holder in all 50 states and the District of Columbia; the federal Drug Enforcement Agency ("DEA") registrant (No. BP9684627); and the license holder in those jurisdictions in which a home health or similar agency license is required. Therefore, Pentec's pharmacy ships intrathecal medications to an employee, who is also the primary care nurse that administers the medication to the patient. Pentec's shipment, delivery and administration process is described in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

Issue: Follow-up Care – Licensure Requirements

- 1. TDH is concerned about the level of follow-up care and how often the RN visits each patient.**

Patient follow-up care is determined on a case-by-case basis depending on the patient's diagnosis, intrathecal pump refill interval, prognosis, and any changes in status. The patient would receive, at a minimum, the same level of follow-up care that would be provided if care were being performed by the physician directly. For example, if a patient is otherwise stable in his or her status and diagnosis, and the patient's refill interval is every 60 days, then the patient most likely would not have contact with the treating physician until his or her next appointment for a pump refill. Pentec's primary care nurses actually have *more* contact with patients than when patients are being cared for by their physician only. In the example mentioned above, the Pentec nurse would contact the patient not less than every 30 days, either by telephone call or by visit, depending on the particular needs of the patient.

- 2. TDH is concerned about the applicant's patient care plans for physician follow-up of patient.**

As a matter of Pentec policy, documentation of patient visits is always provided to the treating physician immediately following the visit. Also, Pentec's primary care nurses communicate continually with the physician and/or their qualified staff on any changes in the patient's status or any patient needs, whether identified by the nurse or the patient.

Issue: Follow-up Care – Risks Involved

- 1. The continuity of care should lie with the implanting physician or the primary care provider following the patient's release from surgical care, who should order the appropriate medication dosage.**

The intrathecal pump physician is the primary care provider with respect to a patient's intrathecal pump care. The family physician addresses other medical needs. The intrathecal pump physician coordinates the patient's care with the surgeon who implants the pump, including any appropriate medication dosage needed post-operatively. Thereafter, the intrathecal pump physician is the prescribing physician for the patient's intrathecal medication.

- 2. Who is responsible if the patient is admitted to a hospital? In an emergent situation, what if the treating physician does not have admitting privileges at the nearest hospital?**

The patient's admitting diagnosis will determine what physician directs the patient's care. If there are concerns involving the patient's intrathecal pump, the attending physician will consult an appropriate physician with privileges to that particular facility. If the intrathecal pump needs addressed, our nurse can enter the facility and care for the patient following the hospital's credentialing process.

- 3. High risk of overdose due to high conversion ratio requires adequate experience with IPs and with interventional pain medication.**

Pentec nurses attend an intense, in-house classroom and field training program that is ANCC-certified to assure adequate experience and the ability to identify factors in the prevention of and the risks of potential for overdose.

Pentec's pharmacy has more than 30 years' experience in the compounding and preparation of intrathecal medications. It uses various reliable literature sources such as the Polyanalgesic Consensus guidelines to assist prescribing physicians when requested to do so.

- 4. Will patient satisfaction and the quality of delivered services equal the current models for delivery of this care?**

Pentec patient satisfaction surveys are conducted annually. The survey asks patients to assign a rating, on a scale of 1 (lowest) to 5 (highest), in 12 different areas. For each of the past 3 years (2011-2013), the average overall rating has been 4.8 out of 5.0. Survey results are reviewed by Pentec management each year, and unfavorable surveys are investigated by the Vice President of Nursing Services immediately, to ensure that patient concerns are being addressed. Survey results are shared with Pentec's nursing staff, and they are taken into consideration as part of the primary care nurses' performance evaluation process.

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5. In addition to the proposed Nashville home office, does Pentec plan to maintain a 24 hour call center through its parent office in PA or other existing location? If so, please identify the address, the amount of time the center has operated, its staffing plan, the number of home health agencies covered by state and its "call" volume over the most recent 12-month period.

Pentec maintains centralized communications at its headquarters, which is located at 4 Creek Parkway, Boothwyn, Pennsylvania 19061. Pentec has a registered nurse on call 24 hours a day, 7 days a week, to handle patient calls. When a patient call is received, the on-call nurse responds by contacting the appropriate Regional Nurse Manager for the state in which the patient resides, who will then assess and respond appropriately to the patient's needs. (The on-call nurse does not assess or advise patients because he or she may not be licensed to practice in the patient's state of residence. However, the Regional Nurse Manager is licensed to practice professional nursing in each state for which he or she is responsible.) Pentec's Regional Nurse Managers have 24-hour accountability for responding to patient calls.

For the 11-month period from January 1 to November 30, 2014, Pentec responded to 741 total patient calls, of which 445 calls were from Specialty Infusion patients. As of November 30, 2014, Pentec's Specialty Infusion division offered services in 32 states, although the patient census in several of these states is presently very small.

Issue: Secure Medications – Risks Involved

1. **Potential for preparation of medication in a non-sterile environment, diversion risks, and risk of impinging sterility of the medications. Is there information on infection rates in the home with IP services?**

The process of sterile compounding and preparation of intrathecal drugs by Pentec's pharmacy is described in detail in the answer to Question 4, Item A at page 6 of Supplement No. 1 and in the Attachment to Question 4.A at pages 49-52 of Supplement No. 1.

Pentec has experienced a zero nosocomial infection rate.

2. **There may be compounding of drugs. How or where are drugs mixed or are only FDA-approved, commercially available products used?**

Pentec Health utilizes commercially available products to prepare prescriptions except in instances where the physician is prescribing higher concentrations of ingredients or multiple ingredients which will not allow Pentec to achieve the desired final concentrations from utilizing commercially available products.

If mixed, is manipulation or diversion of the product possible once mixed? A physician can mix drugs, and there is nothing in the nursing regulations that prohibits nurses from doing so. TDH has not considered the issue of a nurse mixing drugs in a home.

Every prescription filled by Pentec's pharmacy is reviewed, compounded and verified by experienced pharmacy personnel at various stages of processing, including both before and after compounding. Pentec's nurses have no involvement in the compounding of intrathecal drugs.

Pentec has developed a shipping, storage and delivery protocol designed to ensure continuous Pentec custody of all medication until the time of administration to the patient, thereby keeping the risk of diversion to an absolute minimum. This is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

Dosage is changed based on laboratory values. How will these values be taken and reported?

IT medications do not require laboratory monitoring. Ig-G replacement therapy does include some lab work but any changes to therapy will occur at the next scheduled dosage administration, after being reviewed by Pentec's nursing and pharmacy staff and reported to the treating physician.

When ordered by the physician, blood specimens can be collected by Pentec nurses. In such cases, the nurse would send the specimens to the laboratory (Quest) for analysis, and the laboratory would report the values to Pentec. Once the laboratory values are received, the results are then reported and faxed to the treating physician.

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Home health agency nurses are permitted to draw blood and deliver it to laboratories, adding time and costs as compared to performing this service in the physician's office where there is a laboratory.

Many physicians that do not have an in-office laboratory. If a physician does have a laboratory and the patient visits the physician only for the purpose of laboratory specimen collection and analysis, it may result in additional cost. In comparison, by having Pentec collect and send the specimen while in the patient's home performing other services, a cost saving may arise.

3. What safeguards are in place to ensure security of medications during transport to the home?

As noted above, Pentec has developed a shipping, storage and delivery protocol designed to ensure continuous Pentec custody of all medication until the time of administration to the patient, thereby keeping the risk of diversion to an absolute minimum. This is discussed at length in the answers to Question 4, Item A at page 6 of Supplement No. 1, and to Question 4, Item G at page 13 of Supplement No. 1.

Other Questions:**1. How does a typical IP services home health agency contract read?**

Copies of the relevant agreements are attached to this Supplement as Attachment to Exhibit 2, Other Questions, Item 1. These agreements include the following:

1. "Consent to Treat, Insurance Assignments, Financial Agreement, Authorization to Release Information, & Privacy Notice Acknowledgement"
2. "Addendum to: Consent to Treat, Insurance Assignments, Financial Agreement, Authorization to Release Information, & Privacy Notice Acknowledgement"

2. In what other states does the applicant operate as a licensed pharmacy, home health organization or other type of licensed provider classification?

Pentec operates physical pharmacy facilities in Pennsylvania and Massachusetts, and it is licensed as a resident or non-resident pharmacy, as applicable, in all 50 states and the District of Columbia. Pentec is also licensed as a home health agency or other applicable agency in 13 states.

A table listing Pentec's HHA and pharmacy licensure status nationwide is provided in the answer to Question 4, Item I at pages 16-17 of Supplement No. 1.

3. Does the applicant have any licensure or certification citations and/or enforcement actions within the past three years?

Pentec has not had any licensure or certification citations or enforcement actions within the three-year period ending December 10, 2014.

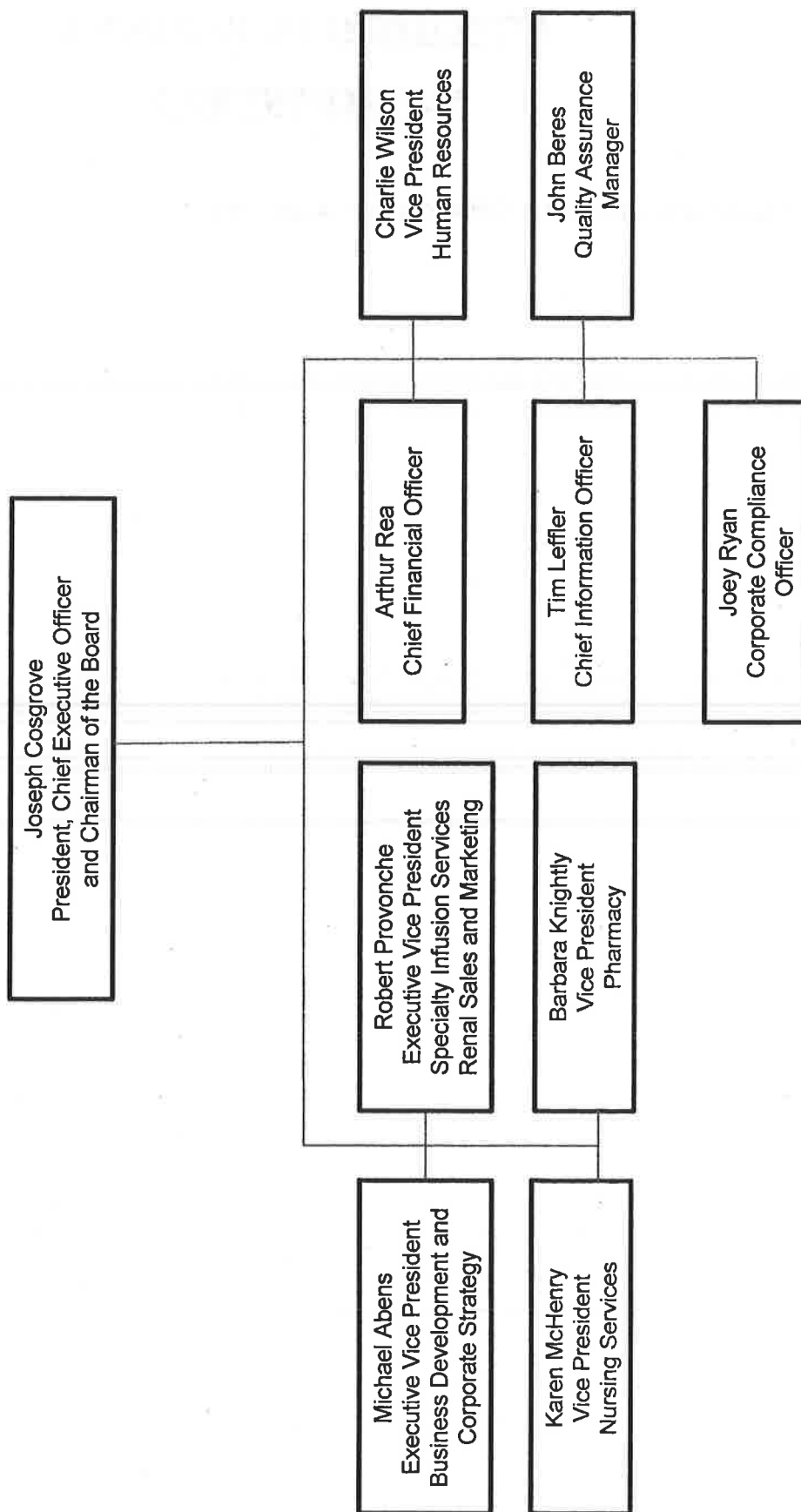
ATTACHMENT TO QUESTION 3**SUPPLEMENT NO. 2**

Pentec Health, Inc. – Executive Office organizational chart.

Pentec Health, Inc.

Executive Office

As of November 30, 2014



December 10, 2014**10:13 am****ATTACHMENT TO QUESTION 3, ITEM 4.F****SUPPLEMENT NO. 2**

1. Copy of Pentec Specialty Infusion Policy and Procedure No. 9.12 – Patient Safety Checklist.
2. Copy of Pentec “Patient Safety Checklist”.

PENTEC HEALTH POLICY/PROCEDURE**DOCUMENTATION****S.I. POLICY AND PROCEDURE****9.12 Patient Safety Checklist****Policy:**

To promote patient safety in refill of intrathecal pumps by implementing check points to confirm the accuracy of medication delivered to the nurse for administration to the patient, confirming the accuracy of medication prior to pump access, and reviewing all changes with the patient or caregiver.

Procedure:

1. Upon receipt of medication delivery (Medication Check In):
 - a) Check all applicable boxes
 - b) If no DOB on script, contact pharmacy to confirm and document accordingly
2. Before Pump Access (for refills and/or adjustments):
 - a) Check all applicable boxes, reviewing out loud with the patient
 - b) Confirm the label of syringe while you read the order
 - c) If data on interrogation is not expected: STOP, CLARIFY, TAKE APPROPRIATE ACTION AND DOCUMENT IN EMR
3. After Pump refill and/or Adjustment:
 - a) Review telemetry with the patient/caregiver or Pentec nurse as appropriate
 - b) Record volume of medication in mLs and alarm date per current telemetry.
Alarm date may vary based on medication stability, or physician/patient preferences
4. Pentec nurse sign form acknowledging accuracy of above information
5. Patient/Caregiver to sign form acknowledging above information reviewed with them by the Pentec nurse
6. Scan form and attach in message center with the title "SAFETY CHECKLIST"

December 10, 2014**10:13 am**

Patient Safety Checklist

Patient Name: _____ DOB: _____

Medication check-in:

- | | |
|--|--|
| <input type="checkbox"/> N/A-adjustment only | <input type="checkbox"/> Bridge bolus will be programmed |
| <input type="checkbox"/> Patient's name and DOB verified | <input type="checkbox"/> New dose is ordered |
| <input type="checkbox"/> No change in medication and/or concentration | <input type="checkbox"/> Last telemetry not available |
| <input type="checkbox"/> Change noted in medication and/or concentration | <input type="checkbox"/> Non-programmable pump |
| <input type="checkbox"/> Patient has a PTM | <input type="checkbox"/> Program is simple continuous |
| <input type="checkbox"/> Last telemetry reviewed | <input type="checkbox"/> Program is flex mode |
| <input type="checkbox"/> Dose will remain the same | <input type="checkbox"/> Discard after date: _____ |

Medication and concentration on label: _____

To be reviewed with the patient prior to performing a refill or adjustment:

- | | |
|---|--|
| <input type="checkbox"/> Patient's name and DOB verified | <input type="checkbox"/> Allergies reviewed |
| <input type="checkbox"/> Data on interrogation is different than last tele. | <input type="checkbox"/> Data on interrogation is the same as last tele. |
| STOP, REVIEW, CLARIFY | <input type="checkbox"/> Non-programmable pump |
| <input type="checkbox"/> Medication on syringe label read out loud | <input type="checkbox"/> Verbally confirm: changes ARE NOT ordered |
| <input type="checkbox"/> Verbally confirm: changes ARE ordered | |

After pump refill and/or adjustment:

- | | |
|--|--|
| <input type="checkbox"/> Telemetry reviewed with patient/caregiver/ facility | <input type="checkbox"/> Telemetry reviewed with Pentec RN |
| <input type="checkbox"/> Non-programmable pump-refill information reviewed with patient/caregiver/facility | |

☐ Total volume is: _____ mLs ☐ Alarm date is: _____

I have ensured the above information is accurate:

Date: _____

The Pentec nurse has reviewed the above information with me:

Date: _____

December 10, 2014**10:13 am****ATTACHMENT TO QUESTION 5, ITEM A****SUPPLEMENT NO. 2**

Copy of letter of support from Comprehensive Pain Specialists (Richard Muench, M.D.),
Hendersonville, Tennessee.

December 10, 2014

10:13 am



131 SAUNDERSVILLE ROAD SUITE 160, HENDERSONVILLE, TN 37075 | WWW.CPSPAIN.COM

December 1, 2014

Dear ,

I am writing in support of Pentec Health, Inc. being granted their certificate of need by the state of Tennessee to become licensed as a home health agency so that patients with intrathecal pumps can be efficiently serviced in their homes.

Intrathecal pumps allow highly concentrated medications for pain and spasticity to be administered through the intrathecal space surrounding the spinal cord. This form of drug administration is very different from the delivery of medication intravenously or subcutaneously and requires highly specialized nursing and pharmaceutical services. Several of my patients have an intrathecal pump because they have not been able to obtain proper relief from traditional treatments for conditions such as chronic pain and/or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke and severe acute pain secondary to cancer.

Currently, these patients must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of few providers in Tennessee that treat patients with intrathecal pumps. We have patients coming from all areas of the state.

Sincerely,

A handwritten signature in black ink, appearing to be "M. [unclear]", written over a horizontal line.

Physician

December 10, 2014**10:13 am****ATTACHMENT TO QUESTION 10****SUPPLEMENT NO. 2**

Copy of affidavit of publication from Tennessee Press Service regarding publication of Pentec's Letter of Intent in Tennessee newspapers of general circulation.

December 10, 2014**10:13 am****AFFIDAVIT**

Saul Ewing, LLP
 2 North Second Street, 7th Floor
 Harrisburg, PA 17101

To Whom It May Concern:

The enclosed itemized statement is for publication of "Notification of Intent To Apply For a Certificate of Need" in the list of newspaper (s) on invoice \$14,3671 on the date (s) stated therein as authorized by your office.


As requested, tearsheets are submitted herewith as further proof of publication.

I, Laurie Alford, Business Controller of Tennessee Press Service, Inc., do hereby certify that the attached is true and correct.

This Twenty Fifth day of November 2014


 Laurie Alford - Business Controller

Sworn before me this 25th day of November 2014


 Robyn N. Gentile, Notary Public
 My commission expires September 11, 2016



December 10, 2014**Tennessee Press Service, Inc.**

Your Print & Digital Connection
 Representing Tennessee Newspapers
 435 Montbrook Lane
 Knoxville, TN 37919-2704

Voice (865) 584-5761 Fax (865) 558-8687

Wednesday, November 19, 2014 09:49 AM

Invoice

Agency Maronetta F. Miller
 Saul Ewing, LLP
 2 North Second Street
 7th Floor
 Harrisburg, PA 17101-

Invoice Date 11/19/2014

PO Number

Order S14.3671

Client Pentec Health, Inc.

Reps State

Earl Goodman

Newspaper

Caption	Run Date	Ad Size	Rate	Rate Name	Color	Disc.	Total
Bristol - Bristol Herald Courier Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 3.5	\$66.40	Public Notice Classified	\$0.00	0.0000%	\$464.80
Chattanooga - Chattanooga Times Free Press Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	\$44.96	Public Notice Classified	\$0.00	0.0000%	\$449.60
Clarksville - The Leaf-Chronicle Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	\$693.18	Public Notice Classified	\$0.00	0.0000%	\$693.18
Cookeville - Herald-Citizen Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 4.5	\$12.73	Classified National	\$0.00	0.0000%	\$114.57
Dyersburg - State Gazette Notification Of Intent To Apply For A Certificate Of Need (AD RAN INCORRECTLY~Reschedule d 11/11/14)	11/09/2014	2 x 7	\$12.45	Classified National	\$0.00	0.0000%	DNR
Notification Of Intent To Apply For A Certificate Of Need	11/11/2014	2 x 7	\$12.45	Classified National	\$0.00	0.0000%	\$174.30
Greeneville - Greeneville Sun Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	\$28.75	Classified National	\$0.00	0.0000%	\$287.50
Jackson - The Jackson Sun Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	\$396.00	Public Notice Classified	\$0.00	0.0000%	\$396.00
Johnson City - Johnson City Press Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 6	\$21.39	Classified National	\$0.00	0.0000%	\$256.68

We appreciate your business! TERMS: Due Net 30 Days

December 10, 2014**Tennessee Press Service, Inc.**

Your Print & Digital Connection
Representing Tennessee Newspapers

435 Montbrook Lane

Knoxville, TN 37919-2704

Voice (865) 584-5761 Fax (865) 558-8687

Wednesday, November 19, 2014 09:49 AM

Invoice

Agency Maronetta F. Miller
Saul Ewing, LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101-

Invoice Date 11/19/2014**PO Number****Order** S14.3671**Client** Pentec Health, Inc.**Reps** State

Earl Goodman

Newspaper

Caption	Run Date	Ad Size	Rate	Rate Name	Color	Disc.	Total
Kingsport - The Kingsport Times-News Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 6	\$32.90	Classified National	\$0.00	0.0000%	\$394.80
Knoxville - Knoxville News Sentinel Notification Of Intent To Apply For A Certificate Of Need	11/09/2014	2 x 9	\$45.64	Public Notice Classified	\$10.00	0.0000%	\$831.52
Memphis - The Commercial Appeal Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 8.5	\$149.00	Public Notice Classified	\$30.00	0.0000%	\$2,563.00
Murfreesboro - The Daily News Journal Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	\$386.46	Public Notice Classified	\$0.00	0.0000%	\$386.46
Nashville - The Tennessean Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 5	\$2,083.14	Public Notice Classified	\$0.00	0.0000%	\$2,083.14
Paris - The Paris Post-Intelligencer Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 7	\$8.85	Classified National	\$0.00	0.0000%	\$123.90
Union City - Union City Daily Messenger Notification Of Intent To Apply For A Certificate Of Need	11/10/2014	2 x 7	\$8.75	Classified National	\$0.00	0.0000%	\$122.50

We appreciate your business! TERMS: Due Net 30 Days

58

270

SUPPLEMENTAL #2**December 10, 2014****TENNESSEE PRESS SERVICE**Your Print & Digital Connection Representing Tennessee Newspapers
tadvertising.biz**Tennessee Press Service, Inc.**Your Print & Digital Connection
Representing Tennessee Newspapers435 Montbrook Lane
Knoxville, TN 37919-2704

Voice (865) 584-5761 Fax (865) 558-8687

Wednesday, November 19, 2014 09:49 AM

Invoice

Agency Maronetta F. Miller
Saul Ewing, LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101-

Invoice Date 11/19/2014**PO Number****Order** S14.3671

Client Pentec Health, Inc.
Reps State

Earl Goodman

Newspaper**Caption****Run Date Ad Size****Rate Rate Name****Color****Disc.****Total****Total Advertising** \$9,341.95**Discounts** \$0.00**Tax: USA** \$0.00**Total Invoice** \$9,341.95**Payments** \$5,000.00**Adjustments** \$0.00**Balance Due** \$4,341.95

We appreciate your business! TERMS: Due Net 30 Days

59

December 10, 2014**10:13 am****AFFIDAVIT**

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

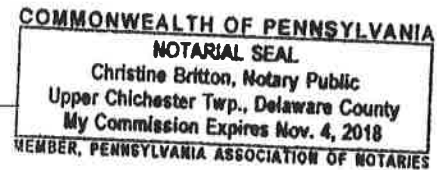
I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.


Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 5 day of December, 2014, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.


NOTARY PUBLIC

My commission expires

11-4-18

COPY- Clarification SUPPLEMENTAL-2

**Pentec Health Inc.
CN1411-046**

Saul Ewing
LLP

COPY

DEC 26 '14 4:58:58
SUPPLEMENTAL

Richard D. Leigh

Phone: (717) 257-7501

Fax: (717) 257-7599

rleigh@saul.com

www.saul.com

December 20, 2014

VIA FEDERAL EXPRESS (Tel. 615-741-2364)

State of Tennessee
Health Services and Development Agency
Attention: Jeff Grimm
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, Tennessee 37243

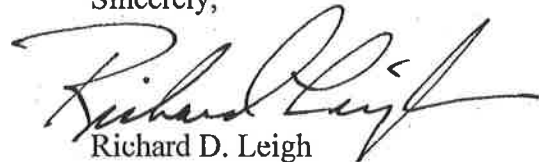
Re: Pentec Health, Inc. / Certificate of Need Application CN1411-046 / Additional Clarification to Supplement No. 2

Dear Mr. Grimm:

In response to your letter to Doug Wynd of December 19, 2014, we are submitting for review one original and two copies of Pentec's Additional Clarification to Supplement No. 2 to Certificate of Need Application CN1411-046, together with the appropriate affidavit.

If you have any questions about the Certificate of Need application, please feel free to contact me (contact information provided above), or contact Doug Wynd at 636-751-6481 or dwynd@pentechealth.com. Again, we look forward to working with the Agency in connection with Pentec's application.

Sincerely,



Richard D. Leigh

Enclosure

cc: Doug Wynd, Pentec Health, Inc.
Robert A. Provonche, Pentec Health, Inc.
Karen McHenry, R.N., Pentec Health, Inc.

PENTEC HEALTH, INC.
ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2
TO
CERTIFICATE OF NEED APPLICATION CN1411-046

DECEMBER 2014

1. Section C, Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

The applicant notes that letters of support will be provided in a future supplemental response. An update was provided by e-mail on 12/16/14. Please provide a response for the following items:

A. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

As in other states, Pentec expects that physicians practicing in the areas of pain management and spasticity would be its most likely referral sources in Tennessee. Pentec will continue to seek letters of support from Tennessee physicians who are possible referral sources, and will provide copies of these letters as they are received.

B. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

Because Pentec is not presently licensed to provide home health services, it does not have Tennessee intrathecal pump patients who can offer letters indicating their need for in-home services.

However, Pentec notes that the letter provided by Dr. Richard Muench of Comprehensive Pain Specialists (Attachment to Question 5, Item A, in Supplement No. 2 to the CON application) states that intrathecal pump patients "must come to my office for pump refills and maintenance, which for them is both costly and inconvenient. If Pentec Health's application is approved, I can direct Pentec's qualified providers to deliver these services and monitor my patients' conditions in a more efficient manner. We are one of the few providers in Tennessee that treat patients with intrathecal pumps. We have patients coming from all areas of the state."

2. Proof of Publication

As noted previously, confirmation of newspapers of general circulation in 3 counties remains an open item under review (Hancock, Perry and Van Buren Counties). Please document the status update provided in your 12/16/14 e-mail, including any additional clarification from Mr. Goodman of the Tennessee Press Association that may have been provided since 12/16/14.

Pentec believes that there are differences of opinion with respect to newspaper coverage of Hancock, Perry and Van Buren Counties. Pentec has relied primarily on the Tennessee Press Service ("TPS") of the Tennessee Press Association ("TPA") to ensure that proper coverage was achieved. On November 19, 2014, Pentec's counsel received the following statement by email from Mr. Earl Goodman of the TPS in response to its inquiry about these three counties:

"Hancock and Van Buren counties currently do not have TPA member newspapers serving those communities and could only be reached by publishing in neighboring counties; Perry County is served by a county-wide newspaper which does not circulate

outside its borders. However, two of our largest public notices customers, the Tennessee Department of Transportation and the Tennessee Department of General Services/Department of Finance, have designated certain papers as region-wide publications, meaning those papers sufficiently cover a number of counties and satisfy the publication needs of their offices. In the case of the Pentec advertisements, the following papers in which you placed notices would cover the counties in question:

*Hancock - Knoxville News Sentinel (the Greeneville Sun also extends into that county)
Van Buren - Chattanooga Times Free Press (the Cookeville Herald-Citizen also extends into that county)
Perry - Nashville's Tennessean"*

A letter from Mr. Goodman dated December 19, 2014, affirming the foregoing and providing further clarification as to the adequacy of Pentec's publication of its Letter of Intent is attached to this Additional Clarification to Supplement No. 2 as Attachment to Question 2.

We have also been advised by the *Knoxville News Sentinel* that it distributes to subscribers in Hancock County by US Mail; by *The Tennessean* that it does not have a defined coverage area and that it occasionally covers news within Perry County; and by the *Cookeville Herald-Citizen* that it distributes to subscribers in Van Buren County by US Mail. Further, all three newspapers offer online editions. In addition, Pentec's Letter of Intent was placed on the Tennessee Press Service statewide website on November 9 and 10, 2014, in accordance with the requirements of the Tennessee Public Notice Law, Tenn. Code Ann. Section 1-3-120 (2013), effective April 1, 2014. This notice was still online as of December 19, 2014, and may be found at <http://www.publicnoticeads.com/tn/search/results.asp?T=PN>.

Pentec believes that it has satisfied the publication requirement with respect to all 95 counties in Tennessee. However, Pentec would consider a modification of its CON application to exclude Hancock, Perry and Van Buren Counties in the event that the Tennessee Department of Health determines otherwise. Pentec notes that according to U.S. Census Bureau 2010 census data for Tennessee, these three counties had a total of 20,282 residents, out of a statewide population of 6,346,105. Because these three counties represent only 0.32% of Tennessee's population, Pentec believes that such a modification to its CON application would not constitute a substantive change.

ATTACHMENT TO QUESTION 2**ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2**

Copy of letter dated December 19, 2014, from Mr. Earl Goodman of the Tennessee Press Service regarding publication of notices in Hancock, Perry and Van Buren Counties.



SUPPLEMENTAL

December 19, 2014

Ladies and Gentlemen:

Tennessee Press Service would like to address the issue of placements in metropolitan newspapers throughout the state as it relates to the counties of Hancock, Van Buren and Perry.

Hancock and Van Buren counties currently do not have Tennessee Press Association member newspapers serving those communities and could only be reached by publishing in newspapers printed and distributed in neighboring counties. Perry County is served by a county-wide newspaper which does not circulate outside its borders. However, two of our largest public notice customers, the Tennessee Department of Transportation and the Tennessee Department of Finance, have designated certain metropolitan papers as region-wide publications, meaning those papers sufficiently cover a number of counties and satisfy the publication needs of their offices. Using this same criteria followed by TPS for several decades, the following papers would cover the counties in question:

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Van Buren - Chattanooga Times Free Press and Nashville's The Tennessean

Perry - Nashville's The Tennessean

As examples, a TDOT Multimodal notice published in 2013 mentioned Hancock County specifically and was published in the Knoxville News Sentinel as well as the Chattanooga Times Free Press and the Tennessean. A construction project for Lobelville's Tennessee National Guard Armory in Perry County was featured in an ad published in the Tennessean by the Department of Finance and Administration in 2010; Spencer's Fall Creek Falls State Park, Van Buren County, was the subject of a construction notice in the Tennessean in 2013. The Tennessee Department of Transportation, until changes in state laws were made two years ago, published all construction projects notices for the Eastern region in the Chattanooga Times Free Press after switching from the Knoxville News Sentinel; for the Middle region, the state changed from the Tennessean to the Leaf-Chronicle in Clarksville. Both changes were made only due to lower advertising costs involved.

Also, in accordance with the requirements of the Tennessee Public Notice Law (Tennessee Code Annotated Section 1-3-120, effective April 1, 2014), all public notices published by TPS member newspapers post their notices online to a statewide website. Notices are kept online and may be found by visiting the following website:
<http://www.publicnoticeads.com/tn/search/results.asp?T=PN>.

By following the above outlined criteria, any agency--state or otherwise--would satisfy publishing commitments for public notices according to Tennessee state law and standards.

Earl Goodman
 Senior Media Buyer • Tennessee Press Service

DEC 26 11 49:58

AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

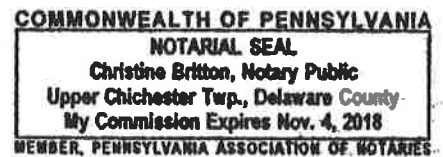
I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 19 day of December, 2014, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

NOTARY PUBLIC

My commission expires

November 4, 2018

Copy

ADDITIONAL
INFORMATION

Supplemental -2

PENTEC Health, INC

CN1411-046

December 30, 2014**10:00 am**

Richard D. Leigh

Phone: (717) 257-7501

Fax: (717) 257-7599

rleigh@saul.com

www.saul.com

December 29, 2014

VIA FEDERAL EXPRESS (Tel. 615-741-2364)

State of Tennessee
 Health Services and Development Agency
 Attention: Jeff Grimm
 Andrew Jackson Building, 9th Floor
 502 Deaderick Street
 Nashville, Tennessee 37243

**Re: Pentec Health, Inc. / Certificate of Need Application CN1411-046 / Additional
 Clarification to Supplement No. 2 (Revised)**

Dear Mr. Grimm:

In response to your letter to Doug Wynd of December 19, 2014, and pursuant to our telephone conversation this afternoon, we are submitting for review one original and two copies of Pentec's Additional Clarification to Supplement No. 2 (Revised) to Certificate of Need Application CN1411-046, together with the appropriate affidavit.

If you have any questions about the Certificate of Need application, please feel free to contact me (contact information provided above), or contact Doug Wynd at 636-751-6481 or dwynd@pentechealth.com. Again, we look forward to working with the Agency in connection with Pentec's application.

Sincerely,



Richard D. Leigh

Enclosure

December 30, 2014

10:00 am

PENTEC HEALTH, INC.

ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2

TO

CERTIFICATE OF NEED APPLICATION CN1411-046

DECEMBER 2014

December 30, 2014**10:00 am**

1. Section C, Need, Item 1 (Specific Criteria: Home Health Services, Item 5 – Documentation of Referral Sources)

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December 30, 2014**10:00 am**

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Perry - Nashville's Tennessean

A letter from Mr. Goodman dated December 19, 2014, affirming the foregoing and providing further clarification as to the adequacy of Pentec's publication of its Letter of Intent is attached to this Additional Clarification to Supplement No. 2 as Attachment to Question 2.

In addition, Pentec's legal counsel has made written and telephonic inquiries to the publications referenced above regarding the geographic areas in which they are distributed. It has been advised (1) by the *Knoxville News Sentinel* that although it does not "distribute" to Hancock County, *News Sentinel* publications distributed to Hancock County are subscriptions delivered by US Mail; (2) by *The Tennessean* that it does not have a defined coverage area and that it occasionally covers news within Perry County; and (3) by the *Cookeville Herald-Citizen* that it distributes to subscribers in Van Buren County by US Mail. Copies of email correspondence from the foregoing newspapers to Saul Ewing LLP, counsel for Pentec, are also attached to this Additional Clarification to Supplement No. 2 as Attachment to Question 2.

Further, all three newspapers offer online editions. In addition, Pentec's Letter of Intent was placed on the Tennessee Press Service statewide website on November 9 and 10, 2014, in accordance with the requirements of the Tennessee Public Notice Law, Tenn. Code Ann. Section 1-3-120 (2013), effective April 1, 2014. This notice was still online as of December 19, 2014, and may be found at <http://www.publicnoticeads.com/tn/search/results.asp?T=PN>.

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December 30, 2014**10:00 am****ATTACHMENT TO QUESTION 2****ADDITIONAL CLARIFICATION TO SUPPLEMENT NO. 2**

1. Copy of letter dated December 19, 2014, from Mr. Earl Goodman of the Tennessee Press Service regarding publication of notices in Hancock, Perry and Van Buren Counties.
2. Copy of email dated December 5, 2014, from *Knoxville News Sentinel* (Louise Watkins) to Maronetta Miller (Paralegal, Saul Ewing LLP, counsel to Pentec) regarding distribution in Hancock County.
3. Copy of email dated December 10, 2014, from *The Tennessean* (Dan E.) to Maronetta Miller (Paralegal, Saul Ewing LLP, counsel to Pentec) regarding distribution in Perry County.
4. Copy of email dated December 5, 2014, from the *Cookeville Herald-Citizen* (Keith McCormick) to Maronetta Miller (Paralegal, Saul Ewing LLP, counsel to Pentec) regarding distribution in Van Buren County.

December 30, 2014**10:00 am**

December 19, 2014

Ladies and Gentlemen:

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<http://www.publicnoticeads.com/tn/search/results.asp?T=PN>.

By following the above outlined criteria, any agency--state or otherwise--would satisfy publishing commitments for public notices according to Tennessee state law and standards.

Earl Goodman

Senior Media Buyer • Tennessee Press Service

435 Montbrook Lane, Knoxville TN 37919

tnadvertising.biz

egoodman@tnpress.com 865.584.5761

December 30, 2014**10:00 am****Leigh, Richard D.**

From: Miller, Maronetta F.
Sent: Friday, December 05, 2014 3:11 PM
Subject: RE: Hancock County is not in our coverage area

Follow Up Flag: Follow up
Flag Status: Completed

PcgIgnoreMessage: 0

PLEASE NOTE: You were BCC'd

To: Watkins, Louise

Thank you.

Maronetta F. Miller, Legal Assistant
Saul Ewing LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101
717.257.7524 (phone)
717.257.7588 (fax)
mmiller@saulewing.com
SaulEwing

From: Watkins, Louise [<mailto:WatkinsL@knoxnews.com>]
Sent: Friday, December 05, 2014 3:09 PM
To: Miller, Maronetta F.
Subject: RE: Hancock County is not in our coverage area

I have checked on this county before - we do not distribute to Hancock County. If there are any News Sentinel publications distributed to that area, it is just mailed subscriptions.

Louise Watkins

Account Manager

KNS Media Group

2332 News Sentinel Drive

Knoxville, TN 37921

(P): 865.342.6515

(F): 865.342.6508

E-mail: WATKINSL@KNOXNEWS.COM

www.knoxnews.com

From: Miller, Maronetta F. [<mailto:MMiller@saulewing.com>]
Sent: Friday, December 05, 2014 2:58 PM
To: Watkins, Louise
Cc: Miller, Maronetta F.
Subject: Hancock County is not in our coverage area

December 30, 2014**10:00 am**

Ms. Watkins, I just left you a vmm. I would like some clarification please... If I place a legal advertisement in the Knoxville News does your distribution cover Hancock County?

Maronetta F. Miller, Legal Assistant
Saul Ewing LLP
2 North Second Street
7th Floor
Harrisburg, PA 17101
717.257.7524 (phone)
717.257.7588 (fax)
mmiller@saul.com

SaulEwing

From: Watkins, Louise [<mailto:WatkinsL@knoxnews.com>]
Sent: Friday, December 05, 2014 2:41 PM
To: Davis, Bonnie Lee
Subject: Hancock County is not in our coverage area

Thank you for your inquiry.

Louise Watkins

Account Manager

KNS Media Group

2332 News Sentinel Drive

Knoxville, TN 37921

(P): 865.342.6515

(F): 865.342.6508

E-mail: WATKINSL@KNOXNEWS.COM

www.knoxnews.com

*Saul Ewing LLP <saul.com> made the following annotations:

~~~~~  
This e-mail may contain privileged, confidential, copyrighted, or other legally protected information. If you are not the intended recipient (even if the e-mail address is yours), you may not use, copy, or retransmit it. If you have received this by mistake please notify us by return e-mail, then delete.  
~~~~~

December 30, 2014

10:00 am

Leigh, Richard D.

From: Miller, Maronetta F.
Sent: Thursday, December 11, 2014 9:27 AM
To: Leigh, Richard D.
Subject: Perry County - Tennessee

Follow Up Flag: Follow up
Flag Status: Completed

FYI

Maronetta F. Miller, Legal Assistant
 Saul Ewing LLP
 2 North Second Street
 7th Floor
 Harrisburg, PA 17101
 717.257.7524 (phone)
 717.257.7588 (fax)
mmiller@saul.com
 Saul Ewing

From: 'customer@tennessean.com' [<mailto:customer@tennessean.com>]
Sent: Wednesday, December 10, 2014 7:00 PM
Subject: RE: Perry County

Thank you for contacting The Tennessean. Where every day matters!

I apologize in advance for not being able to provide you with an exact answer. We cover the Greater Nashville area, but do not have a defined coverage area. We do occasionally cover news within the county. If you have any more specific questions, please let me know.

Sincerely,

Dan E.
 Account Specialist
 The Tennessean
www.MyNewspaperService.com
www.Tennessean.com
 1-800-342-8237

P.S. Our customer service agents can assist you via telephone from 8:00 AM - 7:00 PM Monday through Friday and Sunday from 7:30 AM - 1:00 PM. We are also available by e-mail and Live Chat via our website.

On Fri, Dec 05, 2014 at 12:24 PM, bdavis@saul.com wrote:

December 30, 2014**10:00 am**

Good afternoon, and please pardon my interruption.

I am writing to confirm that the Nashville's Tennessean covers Perry County? I was on the newspaper's website and was unable to locate that information. I believe the case on which we are working needs clarification as to your publication's area of coverage.

I would very much appreciate your response via email. Or, if this email has reached you in error, and you could direct me to whom I should speak, that would be appreciated as well. If you have any questions, please do not hesitate to contact our office.

Thank you.

December 30, 2014**10:00 am****Leigh, Richard D.**

From: Miller, Maronetta F.
Sent: Monday, December 08, 2014 10:07 AM
To: Leigh, Richard D.
Subject: FW: Van Buren County

Follow Up Flag: Follow up
Flag Status: Completed

See below email chain.

Maronetta F. Miller, Legal Assistant
 Saul Ewing LLP
 2 North Second Street
 7th Floor
 Harrisburg, PA 17101
 717.257.7524 (phone)
 717.257.7588 (fax)
mmiller@saul.com

Saul Ewing

From: Keith McCormick [<mailto:keith.mccormick@herald-citizen.com>]
Sent: Friday, December 05, 2014 5:38 PM
To: Davis, Bonnie Lee
Subject: RE: Van Buren County

12-14-2014

To: Bonnie Lee Davis
 RE: Circulation in Van Buren County

The Herald-Citizen is a general circulation newspaper. Most of our deliveries are done by our independent contract carrier force in Putnam and some in surrounding counties. If not delivered by our carriers; it will be delivered by the postal service (which means anywhere).

As of today, we currently have people who subscribe to the print version of the H-C and are being delivered thru the postal service. We also have an e-edition available on-line. One version is free and one is paid available to anyone anywhere.

Sincerely

Keith McCormick
 Circulation Manager

From: Davis, Bonnie Lee [<mailto:bdavis@saul.com>]
Sent: Friday, December 05, 2014 11:23 AM

December 30, 2014**10:00 am**

To: 'circulation@herald-citizen.com'
Subject: Van Buren County

Good afternoon, and please pardon my interruption.

I am writing to confirm that the Cookeville Herald-Citizen covers Van Buren County? I was on the newspaper's website and was unable to locate that information. I believe the case on which we are working needs clarification as to your publication's area of coverage.

I would very much appreciate your response via email. Or, if this email has reached you in error, and you could direct me to whom I should speak, that would be appreciated as well. If you have any questions, please do not hesitate to contact our office.

Thank you.

Bonnie Lee Davis
Practice Assistant to:
Eric L. Brossman, Esquire
Catherine E. Walters, Esquire
Naillah I. Rogers, Esquire

=====

Saul Ewing LLP
2 North 2nd Street, 7th Floor
Harrisburg, PA 17101
Direct: 717.257.7568

"Saul Ewing LLP <saul.com>" made the following annotations:

This e-mail may contain privileged, confidential, copyrighted, or other legally protected information. If you are not the intended recipient (even if the e-mail address is yours), you may not use, copy, or retransmit it. If you have received this by mistake please notify us by return e-mail, then delete.

December 30, 2014

10:00 am

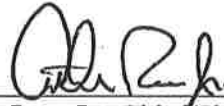
AFFIDAVIT

COMMONWEALTH OF PENNSYLVANIA

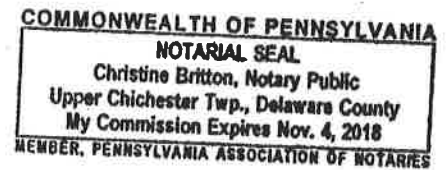
COUNTY OF DELAWARE

NAME OF FACILITY: Pentec Health, Inc.

I, Arthur Rea, Jr., after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Arthur Rea, Jr., Chief Financial Officer

Sworn to and subscribed before me, a Notary Public, this the 29 day of December, 2014, witness my hand at office in the County of Delaware, Commonwealth of Pennsylvania.

NOTARY PUBLICMy commission expires 11-4-18

March 5, 2015

Ms. Melanie Hill, Executive Director
Health Services and Development Agency
Andrew Jackson Building, 9th Floor
502 Deaderick Street
Nashville, TN 37243

RE: Pentec Health, Inc., CN1411-046 **OPPOSITION LETTER**

Dear Ms. Hill:

We are aware of the intent of Pentec Health, Inc. to establish a new Home Health Care service organization to provide specialty infusion services (patients with intrathecal pumps and patients receiving immunoglobulin-G replacement therapy) to all 95 counties in the State of Tennessee from one office in Nashville. **NHC has serious concerns regarding numerous aspects of the referenced CON application including but not limited to whether there is a demonstrated need in the State of Tennessee for such services, whether or not the proposed service delivery model is even legal in the State, that approval of said application would duplicate existing similar services already approved by HSDA, and that the project would adversely impact the existing home health care delivery system. Therefore, I am writing this letter in opposition to the referenced project pursuant to T.C.A., Section 68-11-1609(g) (1).**

In recent months, there has been an alarming trend of applicants requesting Home Care CON's to service all 95 counties in Tennessee with limited staff, single office locations and with a single specialty focus that will do nothing more than further fragment the health care delivery system in our State. In addition, these recent CON's appear to fall outside the established criteria for the home care service. Consequently, it would seem appropriate that until further study is conducted on what criteria should actually be used to evaluate said CON's, a moratorium should be imposed on CON's of this type prohibiting their acceptance and review before the agency

In summary, I am opposed to this CON and ask that it not be approved. There are many unanswered questions regarding this application and more than adequate existing providers delivering high quality home health services to populations of all race and payment source. If you need any additional information please do not hesitate to call me.

Sincerely,

NHC/OP, L.P. d/b/a NHC HomeCare



Lisa Reed, RN
Vice President/HomeCare

Cc: Mr. Doug Wynd
Pentec Health, Inc.
4 Creek Parkway
Boothwyn, PA 19061

**CERTIFICATE OF NEED
REVIEWED BY THE DEPARTMENT OF HEALTH
DIVISION OF POLICY, PLANNING AND ASSESSMENT
615-741-1954**

DATE: February 27, 2015

APPLICANT: Pentech Health, Inc.
424 Church Street, Suite 2000
Nashville, Tennessee 37219

CN1411-046

CONTACT PERSON: Doug Wynd, National Sales Director
Specialty Infusion
4 Creek Parkway
Boothwyn, Pennsylvania 19061

COST: \$142,028

In accordance with Section 68-11-1608(a) of the Tennessee Health Services and Planning Act of 2002, the Tennessee Department of Health, Division of Policy, Planning, and Assessment, reviewed this certificate of need application for financial impact, TennCare participation, compliance with *Tennessee's State Health Plan*, and verified certain data. Additional clarification or comment relative to the application is provided, as applicable, under the heading "Note to Agency Members."

SUMMARY:

The applicant, Pentech Health, Inc., located at 424 Church Street, Suite 2000, Nashville, Tennessee, 37219 seeks Certificate of Need (CON) approval for the establishment of a Home Health Organization and the initiation home health services consisting of specialized skilled nursing services under physician-ordered plans of care to (1) patients with implanted intrathecal pumps and (2) patients receiving immunoglobulin-G replacement therapy through intravenous or subcutaneous infusion, in the patients' places of residence. The organization will serve the entire state with the exception of Hancock, Perry, and Van Buren counties, from its office in Nashville.

The applicant will lease an 87 square foot office at a cost of \$8,028 annually. The cost per square foot is \$92.28.

The total estimated project cost is \$142,028 and will be funded through cash reserves as documented by the Chief Financial Officer in Attachment C, Economic Feasibility.

GENERAL CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all of the general criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

NEED:

The applicant's designated service area includes the entire State of Tennessee with the exception of Hancock, Perry, and Van Buren counties.

The population and Need for these counties are located in Attachment 1 following the Specific Criteria.

Pentech Health, Inc. proposal involves the establishment the establishment of an HHA that will provide very specialized services to a complex and underserved category of patients in Tennessee, specifically those individuals with implanted intrathecal pumps, and those in need of immunoglobulin-G replacement therapy through IV or subcutaneous infusion. Both categories may be considered chronically ill. The applicant asserts this proposal will improve the health of these

patients.

The patients the applicant intends to provide services to suffer from conditions such as chronic pain or spasticity of various origins, advanced multiple sclerosis, cerebral palsy, spinal cord or brain injury, head trauma, paralysis, stroke, and severe acute pain secondary to cancer. Many of these patients have failed to find relief from more traditional treatments and could find relief from intrathecal pump therapy. Some of these patients are able to resume many normal activities as a result of intrathecal treatments.

Pentech estimates about 1,976 people are presently using intrathecal pumps in Tennessee. The applicant states relatively few physicians practice in this specialty and home health services are very limited. Most patients currently receive visits only every 30 days. For patients who are home-bound or who have limited mobility, physician office visits are burdensome. Missed appointments may cause a potentially life threatening situation. Because Pentech provides services to its patients in their home, and because its specially-trained nurses are available on a 24/7 basis, Pentech believes that can eliminate both travel burdens and the serious risks to patients from failure to have their pumps filled in a timely manner.

Additionally, Pentech estimates that approximately 1,020 Tennessean are present in need of Ig-G replacement therapy. These patients have compromised immune deficiencies that require lifetime treatment on a monthly basis, or auto-immune deficiency which may require lifetime treatment on a 3 – 6 -12 month therapy segment.

Pentech reports their proprietary technology will further enhance access to care by patients. This technology includes a centralized communication system that allows patients to reach their primary care nurse 24/7 on a patient portal on Pentech's web site that enables the patient to have access to their medical records and permits secure, HIPPA-compliant communication with Pentech: as well as a secure, two-way videoconferencing capability that allows physicians to observe treatment by Pentech's nurse and communicate with the nurse and patient during the in-home visit.

Pentech provides a listing of all States in which they are either licensed as a pharmacy and a home health agency (if required); Medicare or Medicaid certified, and accreditation in Supplement 1, page 17.

TENNCARE/MEDICARE ACCESS:

The applicant is only certified as a Pharmacy/DME by Medicaid and Medicare. They will not seek Medicaid and Medicare certification for this project.

The applicant estimates gross year one Medicare revenues are \$21,545 or 7% of gross revenues. Medicaid revenues are estimated to be \$21,545 or 7% of total revenues. First year commercial insurance is estimated to be \$261,483 or 86% of total gross revenues.

ECONOMIC FACTORS/FINANCIAL FEASIBILITY: FACTORS/FINANCIAL FEASIBILITY:

The Department of Health, Division of Policy, Planning, and Assessment has reviewed the Project Costs Chart, the Historical Data Chart, and the Projected Data Chart to determine if they are mathematically accurate and the projections are correct based on the applicant's anticipated level of utilization. The location of these charts may be found in the following specific locations in the Certificate of Need Application or the Supplemental material:

Project Costs Chart: The Project Cost Chart is located on page 40 of the application. The total estimated project cost is \$142,028.

Historical Data Chart: The Historical Data Chart is located on page 44 of the application. Pentech Health, Inc. revenues are derived from their Renal Nutrition and Specialty Infusion divisions and they are unable to specify a single unit of measurement for the purpose of completing the Historical Data Chart. The applicant's net operating

revenues for 2011, 2012, and 2013 were \$8,458,000, (\$41,262,000) and (\$2,857,000) each year, respectively.

Projected Data Chart: The Projected Data Chart is located on page 46 of the application. The applicant projects 20.2 and 52.4 patients in years one and two, with net operating income of (\$1,251) \$ and \$117,812 each year, respectively.

The applicant provided the average charges, deductions, net charge, and net operating income for Year 1 below.

	CY2015
Patients	20.2
Average Gross Charge Per visit	\$2,517
Average adjustment per patient	\$164
Average Net Charge (Net Operating Revenue) per patient	\$2,354

CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTHCARE:

Pentech lists all healthcare providers, working relationships, contractual agreements, and transfer agreements on page 57 and 58 of the application.

Pentech is currently establishing relationships with physicians who practice in the field of intrathecal medicine in Tennessee. Pentech believes the patients treated in physician's offices may affect those practices' utilization to a limited extent. The applicant believes their services could offer a tangible benefit to the health care system by offsetting the effect on this utilization by providing services in the patient residence while improving access and quality. Reimbursable costs associated intrathecal refills are likely to be lower than the same services provided by a physician's office visit, resulting in a savings to the healthcare system. It is also likely there will be fewer incidences of intrathecal patients presenting to the hospital with related problems. Finally, the need for emergency transport would be reduced. If the proposed project was implemented, the applicant believes a further affect would be the reduction of the costs associated with services provided to intrathecal patients, thus resulting in financial competition among providers.

There are currently no Home Health Agencies providing intrathecal services in Tennessee. The applicant believes there should be no negative impact on current providers.

Pentech's proposed staffing will be 1.0 FTE registered nurse initially. Their average ratio is 40 patients to 1 nurse. As their census increases, additional full-time primary care nurses will be hired. Pentech reports they have a pool of registered nurses licensed to practice in Tennessee who are able to provide part-time or back-up staffing if needed.

Additionally, Pentech has allocated 1/5 for a Regional Nurse Manager (0.2 FTE).

Pentech does not offer training or access to health care professional schools.

The applicant will seek licensure from the Department of Health, Board for Licensing Health Care Facilities, and is accredited by The Joint Commission.

Not to Agency Members: Pentech received a notice from the Indiana State Department of Health dated August 22, 2011 alleging a breach of the licensure requirements of Ind. Code § 16-27-1-410 and Ind. Admin. Code § 17-10-1 (a) at docket number AC-227-11. This is attached in Attachment C, Contribution to the Orderly Development of Health Care, Item 8. A civil penalty of \$10,000 was paid by Pentech.

SPECIFIC CRITERIA FOR CERTIFICATE OF NEED

The applicant responded to all relevant specific criteria for Certificate of Need as set forth in the document *Tennessee's State Health Plan*.

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.

Please see Attachment 1.

2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

*There is no need for Home Health Services in Tennessee. The Department of Health, Division of Policy, Planning, and Assessment, calculated the need for Home Health Services to be a **surplus of 80,773**.*

3. Using recognized population sources, projections for four years into the future will be used.

Please see Attachment 1.

4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, estimation will be made as to how many patients could be served in the future.

*There is no need for Home Health Services in Tennessee. The Department of Health, Division of Policy, Planning, and Assessment, calculated the need for Home Health Services to be a **surplus of 80,773**.*

5. Documentation from referral sources:

- a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.

The applicant supplies a letter from William Muench, MD of Hendersonville, Tennessee, a physician with Comprehensive Pain Specialists. It does not appear that the applicant adequately meets this criterion.

- b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.

The applicant states the referring physicians would be those who refer their patients to do all pump refills, titrations, and changes in status in the homecare setting.

- c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.

The applicant provided no letters from potential patients or providers who have attempted to find such services but were unable find them.

- d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

No other agency currently provides this service in Tennessee.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.
- a. The average cost per visit by service category shall be listed.
- b. The average cost per patient based upon the projected number of visits per patient shall be listed.

The applicant provided the average charges, deductions, net charge, and net operating income for Year 1 below.

	CY2015
<i>Patients</i>	<i>20.2</i>
<i>Average Gross Charge Per visit</i>	<i>\$2,517</i>
<i>Average adjustment per patient</i>	<i>\$164</i>
<i>Average Net Charge (Net Operating Revenue) per patient</i>	<i>\$2,354</i>

Attachment 1

Joint Annual Report of Home Health Agencies - 2013 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2018 vs. 2013)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Tennessee	1,619	1,457	175,924	6,528,014	0.0269	6,833,509	184,157	102,503	(81,654)
Anderson	22	19	2,893	76,182	0.0380	77,851	2,956	1,168	(1,789)
Bedford	20	19	1,120	46,700	0.0240	50,566	1,213	758	(454)
Benton	11	10	667	16,315	0.0409	16,104	658	242	(417)
Bledsoe	10	8	462	12,698	0.0364	12,599	458	189	(269)
Blount	18	18	2,507	126,809	0.0198	135,171	2,672	2,028	(645)
Bradley	16	14	2,021	102,235	0.0198	107,481	2,125	1,612	(512)
Campbell	21	18	1,715	41,163	0.0417	42,566	1,773	638	(1,135)
Cannon	19	16	423	14,013	0.0302	14,540	439	218	(221)
Carroll	13	13	1,246	28,213	0.0442	27,831	1,229	417	(812)
Carter	12	11	2,072	57,228	0.0362	57,680	2,088	865	(1,223)
Cheatham	24	25	772	39,603	0.0195	40,765	795	611	(183)
Chester	14	13	563	17,355	0.0324	17,999	584	270	(314)
Claiborne	19	15	2,002	32,457	0.0617	33,280	2,053	499	(1,554)
Clay	8	6	250	7,719	0.0324	7,673	249	115	(133)
Cocke	16	14	1,467	36,330	0.0404	38,615	1,559	579	(980)
Coffee	20	16	1,874	53,784	0.0348	56,841	1,981	853	(1,128)
Crockett	13	12	537	14,568	0.0369	14,683	541	220	(321)
Cumberland	15	13	1,601	57,370	0.0279	60,292	1,683	904	(778)
Davidson	32	32	14,912	649,507	0.0230	682,330	15,666	10,235	(5,431)
Decatur	17	14	638	11,773	0.0542	12,080	655	181	(473)
DeKalb	21	16	469	18,918	0.0248	19,125	474	287	(187)
Dickson	25	24	1,617	50,596	0.0320	51,964	1,661	779	(881)
Dyer	11	10	1,671	38,205	0.0437	38,427	1,681	576	(1,104)
Fayette	26	23	713	40,081	0.0178	44,888	799	673	(125)
Fentress	10	7	1,015	18,290	0.0555	18,987	1,054	285	(769)
Franklin	17	12	1,424	41,099	0.0346	42,122	1,459	632	(828)
Gibson	15	14	1,924	50,748	0.0379	52,163	1,978	782	(1,195)
Giles	12	11	1,001	29,325	0.0341	29,285	1,000	439	(560)
Grainger	22	20	886	22,994	0.0385	23,675	912	355	(557)
Greene	20	17	2,454	69,888	0.0351	71,594	2,514	1,074	(1,440)
Grundy	18	16	529	13,396	0.0395	13,293	525	199	(326)
Hamblen	19	17	2,835	63,763	0.0445	65,570	2,915	984	(1,932)
Hamilton	16	16	8,038	345,447	0.0233	353,577	8,227	5,304	(2,924)
Hancock	14	11	682	6,652	0.1025	6,640	681	100	
Hardeman	17	15	917	26,492	0.0346	26,067	902	391	(511)
Hardin	16	14	1,157	25,968	0.0446	26,244	1,169	394	(776)
Hawkins	21	18	2,148	57,273	0.0375	58,164	2,181	872	(1,309)
Haywood	15	13	612	18,199	0.0336	18,009	606	270	(335)
Henderson	14	13	1,015	28,080	0.0361	28,631	1,035	429	(605)
Henry	10	10	1,283	32,595	0.0394	32,956	1,297	494	(803)
Hickman	18	17	725	24,393	0.0297	24,698	734	370	(364)
Houston	12	11	281	8,358	0.0336	8,447	284	127	(157)
Humphreys	16	14	803	18,488	0.0434	18,561	806	278	(528)
Jackson	12	11	402	11,355	0.0354	11,495	407	172	(235)
Jefferson	20	19	1,749	53,006	0.0330	56,872	1,877	853	(1,023)
Johnson	5	5	907	18,126	0.0500	18,127	907	272	(635)
Knox	24	23	9,976	448,093	0.0223	475,569	10,588	7,134	(3,454)
Lake	6	5	325	9,795	0.0332	9,468	314	142	(172)

Joint Annual Report of Home Health Agencies - 2013 Final*
Comparison of Population Based Need Projection vs. Actual Utilization (2018 vs. 2013)**

Service Area	Agencies Licensed to Serve	Agencies Report Serving	Total Patients Served	Estimated 2013 Pop.	Use Rate	Projected 2018 Pop.	Projected Capacity	Projected Need (.015 x 2018 Pop.)	Need or (Surplus) for 2018
Lauderdale	14	11	857	27,465	0.0312	27,125	846	407	(440)
Lawrence	15	12	1,667	42,280	0.0394	42,387	1,671	636	(1,035)
Lewis	12	10	402	12,111	0.0332	12,224	406	183	(222)
Lincoln	14	12	1,062	33,979	0.0313	35,697	1,116	535	(580)
Loudon	23	21	1,572	50,356	0.0312	53,192	1,661	798	(863)
McMinn	17	17	1,807	53,004	0.0341	54,203	1,848	813	(1,035)
McNairy	15	13	1,089	26,408	0.0412	27,299	1,126	409	(716)
Macon	17	15	849	22,957	0.0370	24,121	892	362	(530)
Madison	16	15	3,121	99,153	0.0315	101,001	3,179	1,515	(1,664)
Marion	16	15	729	28,448	0.0256	28,992	743	435	(308)
Marshall	21	17	816	31,159	0.0262	32,015	838	480	(358)
Maury	23	21	2,412	82,029	0.0294	83,256	2,448	1,249	(1,199)
Meigs	18	16	346	12,064	0.0287	12,643	363	190	(173)
Monroe	19	19	1,517	45,664	0.0332	48,088	1,598	721	(876)
Montgomery	19	20	2,903	184,087	0.0158	200,561	3,163	3,008	(154)
Moore	13	10	97	6,369	0.0152	6,401	97	96	(1)
Morgan	21	21	472	21,826	0.0216	22,004	476	330	(146)
Obion	12	12	1,280	31,536	0.0406	31,222	1,267	468	(799)
Overton	14	11	742	22,376	0.0332	22,967	762	345	(417)
Perry	11	6	258	7,971	0.0324	8,096	262	121	(123)
Pickett	8	6	271	5,045	0.0537	4,943	266	74	(191)
Polk	11	11	427	16,654	0.0256	16,588	425	249	(176)
Putnam	16	14	2,405	75,646	0.0318	82,623	2,627	1,239	(1,387)
Rhea	16	15	927	32,966	0.0281	34,790	978	522	(456)
Roane	24	22	2,354	53,918	0.0437	54,457	2,378	817	(1,561)
Robertson	26	26	1,739	69,336	0.0251	74,371	1,865	1,116	(750)
Rutherford	29	29	5,503	285,141	0.0193	329,446	6,358	4,942	(1,416)
Scott	18	15	835	21,986	0.0380	21,969	834	330	(505)
Sequatchie	14	11	413	14,756	0.0280	16,004	448	240	(208)
Sevier	19	18	2,452	93,637	0.0262	100,362	2,628	1,505	(1,123)
Shelby	27	27	18,064	940,972	0.0192	954,012	18,314	14,310	(4,004)
Smith	17	14	708	19,445	0.0364	20,281	738	304	(434)
Stewart	10	10	339	13,436	0.0252	13,941	352	209	(143)
Sullivan	14	13	5,259	158,451	0.0332	161,136	5,348	2,417	(2,931)
Sumner	26	27	4,160	169,409	0.0246	183,406	4,504	2,751	(1,753)
Tipton	26	22	1,298	63,001	0.0206	67,545	1,392	1,013	(378)
Trousdale	16	14	431	8,046	0.0536	8,582	460	129	(331)
Unicoi	13	11	659	18,334	0.0359	18,511	665	278	(388)
Union	21	18	371	19,231	0.0193	19,605	378	294	(84)
Van Buren	12	11	240	5,456	0.0440	5,474	241	82	(159)
Warren	20	15	2,266	40,299	0.0562	41,155	2,314	617	(1,697)
Washington	16	14	4,181	128,537	0.0325	138,370	4,501	2,076	(2,425)
Wayne	11	9	640	16,887	0.0379	16,724	634	251	(383)
Weakley	13	11	1,180	38,255	0.0308	39,491	1,218	592	(626)
White	14	9	962	26,612	0.0361	27,974	1,011	420	(592)
Williamson	32	32	2,815	198,045	0.0142	223,333	3,174	3,350	176
Wilson	28	31	3,727	121,626	0.0306	133,357	4,086	2,000	(2,086)

*Most recent year of Joint Annual Report data for Home Health Agencies

**Data is projected four years from the year the Home Health data was finalized, not the actual year of Home Health data.

Tennessee Population Estimates 2015 and 2019 *

	Population Estimate 2015				Population Estimate 2019				% Increase	
	Total	65+	%65+		Total	65+	%65+		65+	Total
Tennessee	6,649,438	1,012,937	15.2%		6,894,997	1,134,565	16.5%		12.0%	3.7%
Anderson	76,949	14,986	19.5%		78,123	16,737	21.4%		11.7%	1.5%
Bedford	48,099	7,002	14.6%		51,495	7,778	15.1%		11.1%	7.1%
Benton	16,208	3,763	23.2%		16,071	3,898	24.3%		3.6%	-0.8%
Bledsoe	12,610	2,360	18.7%		12,637	2,569	20.3%		8.9%	0.2%
Blount	129,973	23,812	18.3%		137,058	26,507	19.3%		11.3%	5.5%
Bradley	104,364	16,985	16.3%		108,511	19,036	17.5%		12.1%	4.0%
Campbell	41,783	7,793	18.7%		42,792	8,241	19.3%		5.7%	2.4%
Cannon	14,218	2,550	17.9%		14,631	2,742	18.7%		7.5%	2.9%
Carroll	28,012	5,628	20.1%		27,781	5,828	21.0%		3.6%	-0.8%
Carter	57,359	11,279	19.7%		57,828	12,208	21.1%		8.2%	0.8%
Cheatham	40,088	5,115	12.8%		40,965	6,076	14.8%		18.8%	2.2%
Chester	17,593	2,824	16.1%		18,151	2,951	16.3%		4.5%	3.2%
Claiborne	32,765	6,000	18.3%		33,449	6,471	19.3%		7.9%	2.1%
Clay	7,681	1,733	22.6%		7,684	1,792	23.3%		3.4%	0.0%
Cocke	37,207	6,762	18.2%		39,101	6,905	17.7%		2.1%	5.1%
Coffee	54,817	7,938	14.5%		57,619	7,261	12.6%		-8.5%	5.1%
Crockett	14,611	2,566	17.6%		14,715	2,673	18.2%		4.2%	0.7%
Cumberland	58,340	15,895	27.2%		61,077	15,456	25.3%		-2.8%	4.7%
Davidson	663,151	77,086	11.6%		688,318	88,812	12.9%		15.2%	3.8%
Decatur	11,883	2,583	21.7%		12,156	2,657	21.9%		2.9%	2.3%
DeKalb	18,996	3,448	18.2%		19,172	3,765	19.6%		9.2%	0.9%
Dickson	51,127	7,110	13.9%		52,248	7,795	14.9%		9.6%	2.2%
Dyer	38,246	6,424	16.8%		38,482	6,925	18.0%		7.8%	0.6%
Fayette	41,835	7,271	17.4%		45,963	8,408	18.3%		15.6%	9.9%
Fentress	18,553	3,625	19.5%		19,133	3,935	20.6%		8.6%	3.1%
Franklin	41,391	7,479	18.1%		42,408	7,402	17.5%		-1.0%	2.5%
Gibson	51,412	8,875	17.3%		52,350	9,353	17.9%		5.4%	1.8%
Giles	29,293	5,547	18.9%		29,282	6,036	20.6%		8.8%	0.0%
Grainger	23,236	4,329	18.6%		23,850	4,607	19.3%		6.4%	2.6%
Greene	70,520	14,144	20.1%		71,989	15,120	21.0%		6.9%	2.1%
Grundy	13,322	2,693	20.2%		13,303	2,837	21.3%		5.3%	-0.1%
Hamblen	64,438	11,522	17.9%		65,952	12,198	18.5%		5.9%	2.3%
Hamilton	349,273	57,974	16.6%		354,610	64,174	18.1%		10.7%	1.5%
Marshall	6,645	1,349	20.3%		6,663	1,436	21.6%		6.4%	0.3%
Hardeman	26,231	4,308	16.4%		26,035	4,631	17.8%		7.5%	-0.7%
Hardin	26,075	5,508	21.1%		26,310	5,900	22.4%		7.1%	0.9%
Hawkins	57,741	11,739	20.3%		58,241	13,425	23.1%		14.4%	0.9%
Haywood	18,044	2,821	15.6%		18,032	3,136	17.4%		11.2%	-0.1%
Henderson	28,279	4,892	17.3%		28,743	5,371	18.7%		9.8%	1.6%
Henry	32,766	7,033	21.5%		33,015	7,351	22.3%		4.5%	0.8%
Hickman	24,465	4,076	16.7%		24,784	4,751	19.2%		16.6%	1.3%
Houston	8,413	1,671	19.9%		8,449	1,791	21.2%		7.2%	0.4%
Humphreys	18,519	3,656	19.7%		18,581	3,864	20.8%		5.7%	0.3%
Jackson	11,383	2,385	21.0%		11,520	2,593	22.5%		8.7%	1.2%
Jefferson	54,482	10,334	19.0%		57,707	11,606	20.1%		12.3%	5.9%
Johnson	18,090	3,822	21.1%		18,175	4,014	22.1%		5.0%	0.5%
Knox	459,124	69,186	15.1%		481,044	81,757	17.0%		18.2%	4.8%
Lake	9,676	1,162	12.0%		9,411	1,250	13.3%		7.6%	-2.7%
Lauderdale	27,264	3,922	14.4%		27,135	4,292	15.8%		9.4%	-0.5%
Lawrence	42,373	7,628	18.0%		42,373	8,140	19.2%		6.7%	0.0%

Tennessee Population Estimates 2015 and 2019 *

	Population Estimate 2015				Population Estimate 2019				% Increase	
	Total	65+	%65+		Total	65+	%65+		65+	Total
Lewis	12,112	2,269	18.7%		12,259	2,545	20.8%		12.2%	1.2%
Lincoln	34,624	5,104	14.7%		36,059	4,979	13.8%		-2.4%	4.1%
Loudon	51,495	13,107	25.5%		53,741	14,488	27.0%		10.5%	4.4%
McMinn	53,476	10,126	18.9%		54,457	10,845	19.9%		7.1%	1.8%
McNairy	26,755	5,194	19.4%		27,509	5,568	20.2%		7.2%	2.8%
Macon	23,419	3,775	16.1%		24,366	4,275	17.5%		13.2%	4.0%
Madison	99,971	14,747	14.8%		101,279	16,289	16.1%		10.5%	1.3%
Marion	28,652	5,502	19.2%		29,125	6,031	20.7%		9.6%	1.7%
Marshall	31,413	4,970	15.8%		32,322	5,668	17.5%		14.0%	2.9%
Maur	82,526	12,774	15.5%		83,485	14,550	17.4%		13.9%	1.2%
Meigs	12,331	2,560	20.8%		12,697	2,869	22.6%		12.1%	3.0%
Monroe	46,563	9,325	20.0%		48,648	10,680	22.0%		14.5%	4.5%
Montgomery	191,068	16,969	8.9%		203,460	19,759	9.7%		16.4%	6.5%
Moore	6,364	1,267	19.9%		6,415	1,257	19.6%		-0.8%	0.8%
Morgan	21,870	3,531	16.1%		22,076	3,897	17.7%		10.4%	0.9%
Obion	31,365	5,995	19.1%		31,218	6,347	20.3%		5.9%	-0.5%
Overton	22,593	4,364	19.3%		23,104	4,633	20.1%		6.2%	2.3%
Polk	8,025	1,768	22.0%		8,103	1,953	24.1%		10.5%	1.0%
Pickett	4,998	1,320	26.4%		4,930	1,350	27.4%		2.3%	-1.4%
Polk	16,570	3,341	20.2%		16,609	3,607	21.7%		8.0%	0.2%
Putnam	78,416	11,864	15.1%		83,992	12,498	14.9%		5.3%	7.1%
Rhea	33,767	6,217	18.4%		35,081	6,907	19.7%		11.1%	3.9%
Roane	54,079	11,701	21.6%		54,631	12,863	23.5%		9.9%	1.0%
Robertson	71,437	8,312	11.6%		75,312	9,689	12.9%		16.6%	5.4%
Rutherford	302,237	28,650	9.5%		338,904	34,874	10.3%		21.7%	12.1%
Scott	21,915	3,615	16.5%		22,021	3,927	17.8%		8.6%	0.5%
Sequatchie	15,246	2,916	19.1%		16,270	3,372	20.7%		15.6%	6.7%
Sevier	96,116	17,434	18.1%		101,929	19,842	19.5%		13.8%	6.0%
Shelby	946,559	112,753	11.9%		956,200	129,543	13.5%		14.9%	1.0%
Smith	19,771	3,134	15.9%		20,468	3,496	17.1%		11.6%	3.5%
Stewart	13,659	2,549	18.7%		14,027	2,785	19.9%		9.3%	2.7%
Sullivan	159,494	34,287	21.5%		161,707	38,477	23.8%		12.2%	1.4%
Sumner	175,054	26,272	15.0%		186,146	30,856	16.6%		17.4%	6.3%
Tipton	64,759	8,414	13.0%		68,477	9,778	14.3%		16.2%	5.7%
Trousdale	8,275	1,275	15.4%		8,667	1,431	16.5%		12.2%	4.7%
Unicoi	18,419	4,029	21.9%		18,558	4,318	23.3%		7.2%	0.8%
Union	19,347	3,287	17.0%		19,677	3,789	19.3%		15.3%	1.7%
Van Buren	5,433	1,149	21.1%		5,488	1,286	23.4%		11.9%	1.0%
Warren	40,662	6,823	16.8%		41,362	7,339	17.7%		7.6%	1.7%
Washington	132,599	22,369	16.9%		140,184	24,871	17.7%		11.2%	5.7%
Wayne	16,815	3,063	18.2%		16,691	3,286	19.7%		7.3%	-0.7%
Weakley	38,790	5,933	15.3%		39,709	6,292	15.8%		6.1%	2.4%
White	27,132	5,132	18.9%		28,275	5,423	19.2%		5.7%	4.2%
Williamson	207,872	24,219	11.7%		228,670	28,889	12.6%		19.3%	10.0%
Wilson	126,472	18,939	15.0%		135,567	22,683	16.7%		19.8%	7.2%

* 2013 Tennessee Population Projection Series.

Source: Tennessee Department of Health, Division of Policy, Planning and Assessment, Office of Health Statistics.

